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TECHNICAL MANUAL:

An Introduction to the Field of Quality Improvement in Health Care: Applications in Central Asia

**February, 2006
Tashkent, Uzbekistan**



ЗдравПлюс / ZdravPlus

**ENSURING ACCESS TO
QUALITY HEALTH CARE
IN CENTRAL ASIA**

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The views of the author(s) expressed in this publication do not necessarily reflect the views of the United States Agency for International Development or the United States Government.

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Executive Summary

Improving the quality of care has become a priority for all health systems around the world, because of obvious links between healthcare delivery systems and health outcomes. Accumulated experience over the past 20 years has revealed the complexity of healthcare systems as well as many lessons learned from the results of quality improvement efforts. Although there is no universal recipe for improvement across healthcare systems, people in charge of improving quality of care need some directions to start their improvement journey.

This manual gives an overview of the field of quality improvement and presents an improvement logic that might be used either as a step-by-step approach or as a more generic strategy with room for adaptation to local circumstances, depending on the level of responsiveness of the system to be improved.

A quality improvement effort aims at making changes in the healthcare system that address the causes of poor quality. To do so requires implementing an improvement strategy with 3 phases:

1. Identify issues and effective solutions through a small-scale pilot improvement project;
2. Replicate effective changes/interventions and the QI process to the entire healthcare system;
3. Institutionalize an improvement dynamic throughout the healthcare system.

These phases are not always consecutive; they can be simultaneous. For example, the pilot phase can continue discovering new solutions while effective changes are replicated to new geographic areas. The development of a QI policy, to institutionalize improvement mechanisms, does not need to wait until the end of the pilot or activities have been scaled up. For each of these phases, some tools and techniques exist and **Table 1** is summarizing the theory behind them, the expected end-results, and the type of activities involved.

This document presents the theories and activities involved in an improvement effort, from local facility-based activities to the nationwide effort of developing a comprehensive QI policy.

Table 1: Theory and Activities Involved in the Improvement of Quality of Care

	Pilot Small-Scale Quality Improvement Project	Replication of Quality Improvement Processes and Results	Institutionalization of QI Mechanisms
Theories	<ul style="list-style-type: none"> • Quality Management Principles • Quality Improvement Cycles • Quality Assurance Methods 	<ul style="list-style-type: none"> • Diffusion of Innovation • Spread Models • Behavior Change Theory 	<ul style="list-style-type: none"> • Policy Development • Monitoring & Evaluation • Operations Research
Overall goal	Learning about the system	Disseminating changes	Sustaining improvements
Expected Results	Effective system changes and interventions are identified	Best practices (effective changes) are extended geographically through the entire system and produce health impact on the entire population	Mechanisms are in place, which contribute in a coordinated fashion to improving quality of care on a continuous basis
Examples of Activities	<ul style="list-style-type: none"> • Implement a Quality Improvement Cycle: <ol style="list-style-type: none"> 1. Identify the improvement goal and objectives 2. Develop a set of interventions & changes 3. Study the impact of interventions & changes • Develop standards of care/performance • Develop a local quality monitoring system • Document QI activities and results • Disseminate information about QI efforts to decision-makers 	<ul style="list-style-type: none"> • Train new staff in QI • Inform about best practices and evidence-based medicine • Organize special conferences • Integrate QI efforts in regular meetings • Support the spread through supportive facilitation visits • Adapt new solutions to different settings • Publish results of the spread activities 	<ul style="list-style-type: none"> • Implement patients' rights • Promote Evidence-Based Medicine • Develop a National Quality Monitoring System • Carryout new QI projects • Design effective licensing and certification of providers • Develop effective accreditation systems for facilities • Issue evidence-based regulations • Revise policies based on results and evidence

List of Acronyms

AGREE	Appraisal of Guidelines, Research and Evaluation
CA	Central Asia
CPG	Clinical Practice Guideline
CQI	Continuous Quality Improvement
EBM	Evidence-Based Medicine
Hb	Hemoglobin
IMCI	Integrated Management of Childhood Illnesses
IoM	United States Institute of Medicine
MoH	Ministry of Health
PDSA	Plan-Do-Study-Act
QA	Quality Assurance
QI	Quality Improvement
QIP	Quality Improvement Project
QM	Quality Management
RCA	Root-Cause Analysis
SIGN	Scottish Intercollegiate Guidelines Network
SVP	Primary care level facility
TQM	Total Quality Management

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Foreword

The idea to write this document came as we were designing Quality Improvement Activities to support health sector reforms in Central Asia countries. Modern theories of quality management and quality improvement were new concepts in the 5 Central Asian Republics. Instead of trying to write another reference document on these topics, we decided to share our experience in applying quality management theories to improve quality of care. The challenge was to give a sense of what it takes to improve quality in concrete terms, while convincing the audience of the strength of the rationale behind it. For this reason, this document has very specific features:

- It summarizes the experience (and biases) of the authors and the lessons that they have learned from many years of work in the field. As such, it is a mix of theory and practical examples to illustrate specific concepts or techniques.
- It does not target an international audience through “state-of-the-art” techniques, but focuses on delivering information that we feel would be more useful for a region that is building its own experience of quality improvement.
- It avoids the temptation to re-invent a new model for improvement, but builds on the ones that already exist. At the same time, it expands the concept of improvement beyond a facility-based quality improvement effort, up to the development of a national QI policy, in order to place the QI activities in the context of a more ambitious agenda for health sector reform.

We are aware of the limitations of this document, as complex concepts do not always translate well into words. For this reason, feedback would be welcome¹.

As the next phase of the ZdravPlus project is starting (June 2005-May 2010), this document can be a valuable reference to manage improvement efforts and integrated improvement projects.

¹ Send feedback and comments through the ZdravPlus Project website (<http://www.zplus.kz>) or to information@zplus.kz.

How to Use this Manual

This manual can be used in many different ways:

1. As a reference manual during a performance-based training course on Quality Improvement;
2. As a guide for the management of a Quality Improvement effort; or
3. As a stand-alone reference document on the current state of knowledge in quality improvement.

This manual has been written specifically for the following audiences in Central Asia:

- Ministries of Health and their partners;
- Health managers at the regional and peripheral levels;
- Leaders of quality improvement teams; and
- Trainers in quality management and quality improvement.

I. Introduction to Quality and Quality Improvement

About this Document

This document is an introduction to the field of quality applied to the healthcare system. It has been developed in the context of the ZdravPlus² Project, a health sector reform project for the 5 Central Asia republics. It serves as a reference for sensitizing and training different audiences that have a responsibility and an interest in improving the quality of health care services.

Efforts to improve quality are specific in their scope (making changes in a system), focus (achieving well-defined improvement objectives) and processes (following a step-by-step structured approach). Because quality improvement (QI) is not an exact science³, this document does not provide a unique method to improve quality of care. Instead, it gives an overview of the field of QI and focuses on the main lessons learned from the management of improvement projects. By management, we mean the way stakeholders of the healthcare system organize their efforts to improve quality of care, which represents the “art” of making improvement in a system. The field of quality improvement tells us that we are more likely to succeed if we follow a logic that relies on specific principles, concepts and tools.

This document aims at presenting in a simple way the main knowledge that comes from the field of quality improvement. This field is evolving as new knowledge is discovered. In the future, some techniques will be replaced by more effective and efficient ways to manage a quality effort. In the meantime, we hope this document will serve its main purpose of getting readers motivated to start their own journey to improvement and make it enjoyable.

What does Quality of Care Mean?

Everyone has his/her own perception of what quality means, and trying to find a common and universally accepted definition is difficult. For example, The US Institute of Medicine considers that “Quality of care is the degree to which health services for individuals and populations increase the likelihood of desired health outcomes and are consistent with current professional knowledge” (IoM, 1990).

Many other definitions exist, but rather than reproducing them here, we extracted their common denominator, i.e. the essence of the term “quality of healthcare”: it is the **care** patients should receive in accordance to the current medical knowledge and the way the **delivery system** should be organized and funded so that patients receive that care and are satisfied with it. Meeting these criteria requires combining the “science of medicine” and the “art of improvement”:

- Medical knowledge progresses through the results of scientific research published in peer-review journals. The recent concept of Evidence-Based Medicine gives a new dimension to the definition of quality, by extracting some universal knowledge from the systematic review and combination of separate international research studies carried out in very different settings.
- The art of improvement focuses on the identification and implementation of interventions and changes at individuals’ and system’s levels to allow medical knowledge to be applied into practices, so that patients’ and population’s health benefit from it. It is aiming at filling the gap between what we know and what happens to patients in reality (the famous know-do gap).

² More information on ZdravPlus can be found on its website: <http://www.zplus.kz>

³ By this, we mean that it is difficult to predict the outcomes of a specific improvement effort, unlike with the science of medicine where reference to clinical research trials makes the effects of care more predictable.

From the provider's perspective, it is common to think of 3 technical dimensions of quality:

- **Effectiveness** of care means that patients receive the care they need and that care produces the intended effect on health outcomes;
- **Appropriate use** of care means that patients will not receive care that they do not need, has no added value, and generates a waste of resources while posing safety issues;
- **Safe care** means that patients receive the care they need in a way that does not harm them, either through side-effects of drugs or invasive procedures or through the incorrect performance of a clinical task.

From the patient's perspective, quality of care is often judged through criteria that are not mainly technical, but rather relational. Most of the time, patients express their satisfaction (or dissatisfaction) with care in relation to their freedom of choice (of facilities, providers and care alternatives), the time it takes to access services, the way services are organized or integrated in a convenient location, the cost of the care, and the characteristic of their relationships with the providers. Convenience and friendliness of the care are very important to patients and influence patients' use of healthcare services and compliance with the care.

Why should we Improve Quality of Care?

Improvement is what generally drives individuals' decisions in life. The recent focus of many countries on quality of care and the development of a "quality movement" in the health care sector are the results of several driving factors:

- **Patients** are (or want to be) better informed about health issues and more involved in healthcare decisions; demand better services for which they pay; express ever-increasing expectations; organize themselves in associations; are no longer afraid to state dissatisfaction and ask for compensation for medical errors. In other words, patients are more powerful, vocal and proactive users and clients of the healthcare system. Informed and educated patients want to be equal partners to physicians in making healthcare decisions and are more likely to comply with the treatment and use healthcare services more efficiently.
- **Providers** want to deliver better services; need to update their knowledge and skills to keep pace with scientific progress; compete to serve clients; prefer to lead (rather than undergo) the changes that impact the way they practice medicine or deliver care; are more aware of their roles and responsibilities in improving the healthcare system within which they perform.
- **Purchasers** (social systems, government, and private insurance) want to contain the costs of medical services; do not want to reimburse for ineffective and/or harmful care; compete for satisfied clients; want the payment mechanisms to influence the design of better healthcare services at an affordable cost for the society and clients.

What is the Field of Quality Improvement?

Because scientific knowledge evolves, maintaining and improving quality of care requires continuous adaptation of the way the healthcare system responds to health needs of a population. This adaptation happens most of the time through incremental changes in the care model (structure of healthcare services, financing mechanisms and costs of services, regulations for access to care, etc.). This dynamic of changes is very much influenced by the values and constraints of the entire society, including but not limited to: i) individual preferences and differences; ii) common social aspirations; iii) political ideology of the majority in power; and iv) economic environment. The field of quality improvement has developed some techniques that can help individuals and teams identify and implement these changes in a more efficient way.

Although the quality movement started a long time ago in the industry of manufacturing products⁴, its application to health care services is relatively recent and can benefit from three main lessons learned from the industry:

1. ***Quality will improve by design, not by chance:*** a structured effort that relies on sound concepts, applies proven principles and uses specific methods and tools is more likely to succeed than ad hoc and uncoordinated decisions. The improvement process (the way things are done) matters as much as the specific intervention/change (what is done) that comes as a result of this process. Leading a quality effort requires knowledge and skills that can be learned through a specific competency based training, but will only mature with field experience and continuous learning from successes and failures.
2. ***The knowledge base in the field of quality comes from many disciplines:*** statistics, management, public health, clinical care, evidence-based medicine, human psychology, sociology, and anthropology, juts to name a few, all contribute to the success of the quality efforts. The appropriate combination of these disciplines will make the quality improvement journey more effective, although one does not need to be an expert in each of them to be an effective manager of a QI effort. These disciplines contribute to quality improvement by widening the focus of the improvement efforts from “what standards need to be developed and changes to be made?” to “what makes healthcare providers and managers willing to adopt standards and change systems?”. Because of this unique combination of disciplines, the field of quality improvement is different from other health sector disciplines such as medicine or public health (see ***Annex 1*** as a summary of most striking differences).
3. ***Improving quality of care usually requires many changes (at system or individual levels)*** and is rarely the consequence of a unique intervention. Although some interventions obviously influence quality of care (like training staff when there is a competency gap), there is no recipe that guarantees the consistent impact of one or a mix of interventions. For this reason, the in-depth understanding of root-causes of poor quality is often needed, along with the search for creative solutions/interventions. Without changes, the overall system of care will keep producing the level of performance that is currently observed. The focus of the field of QI is on changes: identifying them, implementing them, and assessing their impact.

Specific results are expected from a Quality Improvement effort:

- Increased providers’ compliance⁵ with evidence-based protocols and guidelines;
- Increased health status of the population (measured through mortality and morbidity indicators or other summary measures of population health);
- Increased providers’ motivation and patients’ satisfaction;
- Reduced costs of care and waste of healthcare resources;
- Increased efficiency (better use of resources, increased productivity) and affordability; and
- Reduced number of medical errors.

Delineating the limits of the field of quality improvement in healthcare is an impossible task. Many authors have described various frameworks, models, methods, and tools and there is no universal consensus on a definition of Quality Improvement that would encompass all concepts and approaches. Furthermore, each

⁴ The post-war transformation of the Japanese industry is largely credited to a quality movement.

⁵ Because of the implicit coercive nature of the term “compliance”, providers sometimes prefer to think in terms of “performance according to standards”. The wording is different, but the idea behind it is the same.

author has its own way of explaining similar concepts and techniques and their respective attractiveness depends only on the readers' perceptions and own experience (or lack thereof). Because conceptual frameworks help understand the move from theory to application, we decided to develop such framework as a way for readers to see more concretely "what it takes" to improve quality of care. There is no recipe for quality improvement, but the model presented in Chapter II is an attempt to illustrate the logic of improvement of a system and to understand the structure of this document.

Because the definition of quality sometimes leads to endless debates, the trend is to think more in terms of improvement than just quality improvement. The focus is therefore on the dynamic of improvement, i.e. the process, and not only on the improvement objective, i.e. the content. Obviously one has to define clearly what needs to be improved and, by doing so, provide an operational definition of the concept of quality.

In Short on Quality and Quality Improvement

Patients should receive the care they need, which is known to be effective, and in a way that does not harm them. Patients should not receive care that is not necessary, leading to waste and increased risks of side effects. These 3 aspects (effectiveness, appropriateness, and safety of care) represent a convenient way to define and measure quality of care from the perspective of the supplier (the healthcare system). From the perspective of the receiver (the patient, or client), another aspect is fundamental to the definition of quality: satisfaction with the care received and the way the healthcare system is organized, including choice of services, financing mechanism and cost.

Quality improvement is both a set of concepts and practical techniques and tools that, if used appropriately, can help the healthcare system improve quality of care by identifying and implementing changes in that system and influence individuals' behavior and attitude.

II. A Framework for Quality Improvement in Healthcare

Efforts⁶ to improve the quality of healthcare services usually involve 3 components: 1) The implementation of a small-scale pilot QI project; 2) The large-scale replication of improvements; and 3) The institutionalization of improvement processes. When managing a quality improvement effort, teams are trying to accomplish these various goals with a different time-horizon:

1. ***The short-term goal is to achieve a specific and measurable quality improvement objective through small-scale pilot improvement projects*** (for example, *to increase the proportion of patients under correct treatment for hypertension in three health facilities*). A quality improvement project (QIP) is an excellent way to achieve improvement results that focus on one specific health issue. These QIPs have a defined time limit set by the achievement of expected outputs/outcomes. QIPs represent a unique opportunity for all stakeholders involved to learn more about their healthcare system, and use these lessons for replication of improvement. For easy management and quick learning, a pilot QIP is set up on a small scale, involving few facilities. Small-scale pilot improvement projects allow finding out what system changes and interventions lead to quality improvement. Activities under this component include, but are not limited to:
 - **The development of standards** that define the content of care patients should receive and that would become the objectives of the quality improvement effort. The recent development of methods to review scientific evidence (Evidence-Based Medicine-EBM) is helping develop such clinical standards of care.
 - **The measurement of quality** against standards or objectives, through the establishment of a quality monitoring system that will tell if quality of care is improving or not.
 - **The management of changes** that target the healthcare system and its stakeholders, through the identification and implementation of specific interventions.

The process that helps teams organize their work as a stepwise effort, with a logical sequence of activities such as the ones described above, is known as the QI cycle. **Chapter IV** of this document describes the QI cycle.

2. ***The mid-term goal is to replicate the results*** of the pilot QI projects in order to achieve health outcomes of a significant magnitude. Improving quality of care in 10% of the health facilities will not produce significant health gains, reflected in population health statistics (for example, *to replicate changes and interventions that are proven effective in increasing the proportion of patients under correct treatment for hypertension*). Large-scale replications of successful changes and interventions as well as improvement processes are necessary to improve health outcomes in an entire population and not be limited to a small geographic area. Activities under this component rely on strategies to replicate changes in a system, such as the diffusion of innovation theory and spread models.
3. ***The long-term goal is to institutionalize a quality improvement dynamic*** within the healthcare system (for example, *teams will keep adjusting the monitoring of the quality of care to patients with hypertension according to new evidence on the effectiveness of treatment*). Institutionalization of improvement processes consists of developing mechanisms to initiate and sustain a dynamic of improvement, so that the system keeps

⁶ We use the word “effort” instead of “program” or “project” because the latter are often interpreted as a vertical program/structure, whereas we recommend integrating QI processes into existing structures and activities.

performing the activities mentioned above on a continuous basis, in order to realize the never-ending vision of a better healthcare system. Because they are not limited to specific health conditions, these mechanisms help stakeholders of the healthcare system better define their roles and responsibilities in the improvement of quality of care.

When all types of activities are carried out in a coordinated fashion, the quality improvement process is more likely to produce and sustain results. **Figure 1** presents a framework that integrates all activities into one effort. **Chapter III** provides a summary of the concepts and principles behind the quality improvement theory, while **Chapters IV, IX & X** describe in depth the 3 components of the framework.

In Short on the (Quality) Improvement Framework

An improvement framework should encompass 3 types of activities: i) pilot QI projects aimed at identifying (quality) issues and discovering effective solutions; ii) scaling-up interventions to replicate the effects in an entire healthcare system; and iii) developing a national QI policy to institutionalize a dynamic of improvement.

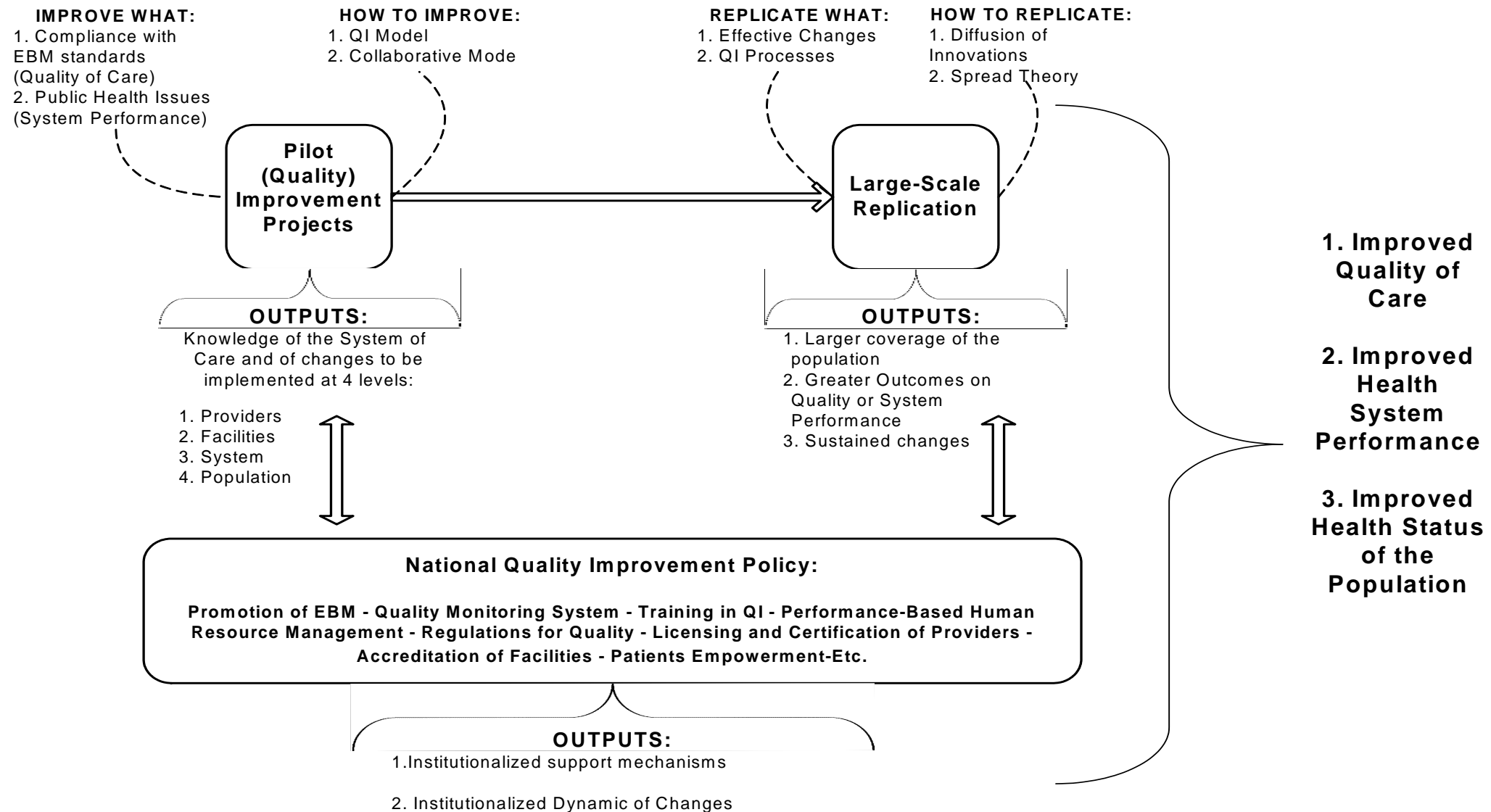
When implementing pilot improvement projects, a team learns about barriers to quality/improvement and the effects of changes/interventions at the level of providers, patients, facilities and system/policies. Health facilities can work simultaneously on the same improvement objective (collaborative mode) or on different ones.

When scaling-up improvement, a team replicates effective changes and interventions to an entire healthcare system, but also replicates the QI processes themselves so that new facilities carry out their own QI cycle on a topic of their choice.

When developing a QI policy, a team designs those mechanisms that support a continuous dynamic of improvement in the healthcare system and that make QI a way of working rather than a time-limited project. Examples of such mechanisms are: training managers in quality improvement; developing a national database of quality indicators; developing mechanisms to address patients' complaints; designing incentives for quality/performance; etc. Because they are not topic-specific, these mechanisms support the other 2 components of this framework.

Fig. 1: The Framework for Quality Improvement:

OVERALL (QUALITY) IMPROVEMENT STRATEGY



III. The Theory of Improvement: Concepts and Principles

Improvement Concepts

Improvement concepts help us “*design*” a quality improvement effort and are relevant to improving quality of care. Three concepts are most useful:

➤ **Quality can always be improved**

Improving quality of care is a dynamic, iterative and continuous process over time with no endpoint. It is important that all people involved in the healthcare system perceive that there is always room for improvement and that they be willing to reach the next level of performance through continuous efforts integrated in their day-to-day work.

➤ **No improvement will take place without changing the “system”.**

To understand this concept the healthcare system could be compared to a factory that produces a certain number of products per year. In order to double this number, some changes/adjustments need to be made to the factory. Morbidity, mortality, immunization coverage are examples of the “products” of the healthcare system. In order to increase immunization coverage, some changes need to be made to the immunization system, such as introducing an active outreach immunization program in complement to regular immunization days at the facility. In other words, ***if we keep doing things the same way, we will keep getting the results that we are getting.*** If we want better results, we need to do things differently. Although it sounds simple, this concept is often hard to apply in real life since acceptance of the concept means a willingness to change. It takes a great deal of negotiations with all participants (government, health workers, patients, health insurers, etc.) and requires strong leadership for changes to take place.

➤ **The success of an improvement effort comes from the learning about the system**

Interventions and changes are just ideas that deserve to be tested before being adopted and replicated on a large scale. A more “scientific” approach consists of implementing the changes on a small scale and deciding to replicate them to the whole healthcare system after demonstration of their effectiveness. This will allow testing the impact of an intervention and studying the implementation processes, as well as avoiding implementing changes that will not be effective on a large-scale. Testing and studying is a key feature of a “learning” organization, one that is constantly innovating to improve its performance. In other words, the success of an improvement effort is not only measured in terms of achieving the initial objectives, but also in the understanding of what explains successes or failures in reaching the objectives.

Quality Management Principles

Quality Management (QM) principles help us “*manage*” a quality improvement effort. We selected 6 that we think are most useful:

- Approach quality of care from the perspective of the patients;
- Think in terms of systems and focus on processes as targets for changes;
- Base any decision on reliable information;
- Make the quality effort a team’s responsibility;
- Communicate expectations, objectives and progress on performance to all stakeholders; and
- Identify and strengthen, or build and sustain leadership in the quality efforts

In the following paragraphs, we will explain these principles and illustrate their application.

Approach quality of care from the perspective of the patients

Providers tend to design services that are convenient for them, but might not be perceived as user-friendly by the patient. For example, a health center will have reduced staff during lunchtime, which is when most working patients could come for a consultation. Responding to the needs of the population would require changing the working hours of the physicians, so that they respond to the load of patients without affecting quality of care. Such change might increase the appropriate use of the services, and satisfaction among patients. Another reason to consider patient's perspectives is because the health system mandate is to serve patients and contribute to the improvement of the health status of a population. When health is considered as a basic right, health systems are designed differently than when health is just another "commodity". This "patient focus" means several things:

1. *Quality of care is also defined by the patients*, according to their needs, but also to their expectations, demands and preferences. Patients' health needs are too often defined only by healthcare providers who think they know best what influences health status and what care should be delivered. Patients have expectations, which are sometimes unrealistic or inconsistent with the medical science, but through which they judge the care they receive. Patients express demands for services in many ways, including their preferences among many health services delivery alternatives. Providers sometimes ignore patients' preferences and do not listen to their demands. Studies of patients' satisfaction allow understanding what criteria patients use to assess the quality of the care they receive and can help us improve the way we design healthcare services.

For example, in one facility of the Issyk-Kul oblast of Kyrgyzstan⁷, when asked about the room where practitioners see patients, clients gave an average score of only 1.6 on a scale of 5. The staff heard that the room wasn't very attractive and provided little privacy, so they created three separate examination rooms, bought flowers, curtains, a painting, soap and towels and, by the second round, clients' scores increased to 2.9 (an increase of 83 percent). By the third round, after further improvements, the score rose to 3.5, a leap of 119 percent over Round 1.

2. *The analysis of the healthcare system must describe what patients are going through*: their flow through the different levels of the system, and their perspectives on the care they receive at each level of the system and each step of the care process. This is an aspect usually not well known by health professionals. A physician would see a patient in his office, in ignorance of what happened before (how long he waited, how well he was received, how far he lives, and living conditions that might influence health) and of what will happen after he leaves (did he understand the recommendations? will he go to the pharmacist? will he get the needed drugs? will he be able to follow any advice in his social, professional and family context?). Even if providers' performance is consistent with standards, there is no guarantee that the care will benefit the patient. The "bigger" system is influencing the outcome of the care, and providers who know better about what the patients go through and understand better the system of care might adapt their practice to benefit more the patient.

For example, the referral of the patient from the primary level of care to the hospital requires physicians to write a referral form with reasons for referral and a description of the care already provided. When results of tests are not written on the form, the hospital will redo the tests, an inconvenience for the patient and waste of

⁷ *Improving the Quality of Reproductive Health Services in Issyk-Kul Oblast, Kyrgyzstan: Report on a Pilot Project*. Noorgoul Seitkazieva, Fatima Kamakhunova, Ton van der Velden, Asta-Maria Kenney, and Alanna Shaikh. March 2002. ZdravPlus Program Document.

resources to the system. If the physician knows this information, then he might pay more attention in providing the details of the results of these tests.

3. *Patients need to play an active role in the quality improvement efforts.* Even the most “progressive” quality efforts give a minor role to patients. The patients usually do not drive the quality efforts. At most, they are “invited” to be part of the teams or express their satisfaction and ideas about changes they would like. The “meaning” of customer-focused care or patient-entered care will become reality when patients take ownership of an improvement effort, and are equal partners to the other stakeholders. Effective ways to promote patients’ ownership in the quality efforts deserve to be studied and innovative mechanisms remain to be discovered. A closer relationship between the health system and its clients improves communications and contributes to more informed demands, more realistic expectations, better use of healthcare services by patients, and higher compliance with treatment schemes.

For example, a recent improvement effort in the US tried to decrease the use of antibiotics for the treatment of acute otitis media in children⁸. Some otitis does not require antibiotics, but some might. It would be irrational to treat all children with antibiotics and it would also be inconvenient for the parents to bring back the child after 1 or 2 days of observation for the prescription of needed antibiotics. For these reasons, physicians write a prescription of antibiotics to all children, and explain to the parents that if the symptoms (mainly pain and fever) do not disappear after 2 days or pain medication (acetaminophen), then they can go buy the antibiotics. At follow-up calls, only 31 percent of the 192 children in the study had had their antibiotic prescriptions filled, 78 percent of the parents said that the pain medications worked, and 63 percent of parents said they would be willing to treat future episodes without antibiotics. Because parents are involved in the decision, the use of antibiotics might decrease by 50% or more.

Think in terms of systems and focus on processes as targets for changes

For a long time, health experts have used a linear inputs/outcomes model: expected results (outcomes) would come from appropriate training and resources (inputs). The way resources were supposed to be used, steps delineated and services organized were not defined in details. In fact, they were overlooked. With the promotion of a system’s view that focuses on processes of care (inputs-process-outcomes), Pr. Avedis Donabedian⁹ helped health planners and managers better understand the healthcare system. Now, teams involved in an improvement effort know that more training for staff and more resources to facilities are not enough to improve the quality of care, but that redesigning the process of care is also needed. This “system-focus” means several things:

1. *A quality effort will often look at the details of each and every step* of the process of care because this is where we usually find most inconsistencies that are source of inefficiency, ineffectiveness, waste and harm to patients¹⁰. True leaders enjoy complexity and are not afraid of dealing with too many details. A quality journey will involve the collection of information on many aspects of the healthcare system, as the investigation of the real causes of poor quality unfolds and sheds new light on other “layers” of influencing factors and their connections. Like “peeling an onion”, the improvement effort uncovers new issues and information as previous problems are solved. One needs to express good judgment on the benefits of additional data collection efforts, or this exercise becomes an endless quest for more information.

⁸ Siegel RM, et al. Treatment of otitis media with observation and a safety-net antibiotic prescription. *Pediatrics* 2003;112:527-531.

⁹ An author of many books on the assessment of quality and quality improvement.

¹⁰ “The devil is in the details”

For example, a team in Ferghana oblast, in Uzbekistan, succeeded to improve the performance of physicians for the treatment of iron-deficiency anemia in women of reproductive age. However, they also noticed that better prescription of iron supplements did not significantly impact the level of anemia in patients. To better understand why, the team investigated what happens after the patient leaves the facility and what are the components of the system of care for these patients. The team ended up interviewing pharmacists to identify issues with the drug supply system (responsible for limited availability and financial accessibility of iron supplements) and the patients themselves, whose healthcare seeking behavior are very much influenced by the family and especially the mother-in-law. These other components of the system of care must be addressed if one wants to achieve a reduction in anemia in this population.

2. *The limits of what we call the healthcare “system” need to be identified* so that it is clear what system we are dealing with. Although “everything is linked to anything else”, it is important to set the borders of the components of the more specific system of care that is the target of the improvement effort. It is equally important to make explicit the functional links between the components. Improving a system requires making changes in its components and their interactions. We might change all the parts of a broken car, but if they are not properly connected to each other, it won’t drive. Identifying the components also helps “categorize” the types of changes and interventions that can be made. The system’s view is a useful representation of a system, but remains limited in explaining the relationships between components. Sometimes, the most effective changes are not in the nature of the components, but in their relationships. In summary, the institutional structure, roles, and relationships in the health sector need to be identified and the right institution needs to be doing the right thing.

The previous example shows that there are very limited interactions between the providers and the pharmacists, and yet they are all parts of the system of care for women with anemia. A better understanding of these links will help design interventions such as improved communication between providers and pharmacists on what drugs will be prescribed by the provider, what drugs are available at the pharmacy, the costs of drugs and a consistent counseling to patients (who tend to make the final decision on which drug to buy, through negotiations with the pharmacists).

3. *Standards of care and services must focus on processes* and all stakeholders of the system need to know what these processes should be. Achievements of expected health outcomes depend rarely only on the internal characteristics of resources (doctors, nurses, equipment, etc.), but come mainly from the organization of healthcare services and processes so as to allow and ensure that the care is consistent with the best possible evidence at that time. Clinical care standards (such as clinical guidelines developed after review of scientific evidence) and management practices (organization of services) both describe processes that lead (or are expected to lead) to better outcomes.

The anemia project in Ferghana found a real weakness in the understanding of patients about the importance of taking their iron pills for 3 months, an issue that might be addressed by strengthening the counseling process both at the health facility and the pharmacy levels.

Base any decision on reliable information

Impressions, personal opinions, and vague statements are not useful for improvement decisions and hence not acceptable. Statements such as “*the staff is always late and patients wait for a very long time*” are not specific enough and might be exaggerated, even when they describe a real issue. It expresses real dissatisfaction that must be taken into account, but which might be more actionable if measurement found that the reality is that “*one staff person comes to work 30 minutes late every other day and the first 5 patients have their appointment delayed*”. Objective measurement makes it also easier to do something about a quality issue, both regarding the magnitude of the problem and the causes. In the previous example, one might find that this staff person is driving her children to school every other day, a cause that might be addressed. This “information-focus” targets 3 types of measurement:

1. Collect data to assess variation in the level of quality, as a way to monitor performance over time, before and after the implementation of interventions and solutions. We want to monitor quality/performance in terms of level of compliance (or gaps) with standards or improvement objectives. Since performance variation is a natural phenomenon, we need to capture this variation over time to know when it truly reflects improvement or not. The correct interpretation of variation in performance is the field of statistical process control. It is an important component of a quality improvement effort, but requires specific skills in the interpretation of control charts. A simpler quality monitoring system can be designed to monitor performance using run charts, by collecting the same indicators on a regular basis and interpreting their trend over time (trend charting). Run charts are useful tools, the interpretation of which does not require statistical tests.

In the Kuva rayon of Ferghana, the anemia improvement team set up a quality monitoring system with the monthly collection of 5 indicators. The team noticed that 100% of women of reproductive age were found having anemia after testing at the primary care facility. The team started to (re)calibrate the Sali hemoglobinometers (the machine/method used to measure level of Hemoglobin) in the rayon, and immediately the prevalence of anemia decreased by 50%.

2. Collect data to identify the root-causes of poor quality or problems. We want to know what the causes are or factors that influence the quality of care in order to develop relevant interventions and avoid a “hit and miss” approach¹¹. Among the many factors that influence quality of care, some might play a more important role than others. According to Pareto (an Italian statistician), 20% of the causes are responsible for 80% of the performance. This 80/20 rule seems convenient and “attractive”, but is not always true. Most of the time, many factors influence the quality of care and their interconnections make them all relevant to take into consideration when designing an intervention. In many instances, a set of factors must be in place for the overall system to perform better and creates an “all or nothing” situation (improving all but one aspect won’t be enough to bring results).

For example, the proper diagnosis of anemia requires 1) having a machine that measures Hemoglobin level in the blood and the corresponding reagents; 2) being trained in the procedure to draw the blood and perform the test; and 3) setting up a calibration system in place to guarantee the accuracy of the results.

3. Collect data to confirm the implementation of changes/interventions. We want to know if the interventions/changes that were planned were implemented and also if they were implemented according to the initial design. It is not rare that interventions are not really implemented as smoothly and completely as they were planned. Sometimes, only part of the intervention is implemented, and this knowledge (as well as the reasons for changing the intervention) is important to interpret the impact. Otherwise, one might discard interventions that are effective.

From the example above, improving the accuracy of the diagnosis of anemia requires that machines be calibrated. To correctly interpret the impact of the calibration process on the incidence of anemia, one needs to make sure that all machines have been calibrated according to an effective calibration process, or the interpretation of the rayon¹² performance will not be accurate.

Make the quality effort a team’s responsibility

It is unlikely that one individual only has control over the entire system and set of processes and that changes and interventions will not require a team effort. Although team involvement can slow down the decision-making process and raise conflicts, teamwork is more likely to promote ownership, strengthen commitment,

¹¹ “Hit and Miss” approaches are interventions based only on assumptions, which do not address the real cause, are tested at random one after the other, and are usually not effective.

¹² A rayon is the administrative structure under the Oblast. It is the equivalent of a district, whereas the oblast is the regional level.

and motivate members who, individually, cannot influence the many components of a usually “complex” system. Hence, making changes in a healthcare system requires inputs from many stakeholders, to identify and implement interventions. This “team-focus” means several things:

1. Stakeholders of the system of care to improve need to be identified because they will constitute the quality team. Knowing the system to improve will help identify the team members: those persons who take part in the delivery of care to patients, those persons responsible for providing the resources (ordering equipment and supplies), and those persons whose decisions influence the work of the others. We might not be able to identify all people involved from the beginning. As the quality “journey” evolves, new issues might be identified that need the involvement of different people and more ad-hoc temporary teams.

For example, to improve the immunization system for children, the following people will need to work together: the reception nurse who identifies the children who need vaccinations; the physician who does the injections; the pharmacist who orders and stores the vaccines; the nurse in charge of sterilizing the needles and syringes; and the patronage nurses who sensitize the population to bring their children for immunization. All contribute to the results of having more children immunized and all are components of the immunization system.

2. Working in teams follows specific rules and is different from a group who meets from time to time. Teamwork is not so natural, and is not usually the way human beings spontaneously organize their work together. It requires special efforts to accept to play the role of a team member for the benefit of the whole group, as well as recognizing others’ roles and following the discipline expressed through ground rules. People must be trained in the skills needed to perform as a team. Entire books have been written on how to work in teams, but the main ideas are extracted here:

- ✓ Team members fulfill different responsibilities and their roles must be explicitly distributed and understood by all: team leader, timekeeper, reporter, facilitator, and regular members. All of them contribute to making the team meetings as productive and efficient as possible.
- ✓ It takes time for a group of people to work as a team, and 5 stages of teamwork have been described: forming (members try to define the way to work with excitement but also some cautious observation of others), storming (members argue and express concerns, question and resist working together), norming (members realize they must work together and accept the challenge), performing (members enjoy working together and achieve their objectives) and closing (the team members discuss their feelings, a mix of pride to have accomplished something and sadness to disband).
- ✓ Team meetings are the key activity of the team, and require good preparation and following explicit rules: full attendance, time management, communication processes, task distribution, breaks, topics, reports, archiving documents, etc.

3. Several teams might be necessary because they fulfill a different role. For the quality efforts we can identify at least 4 types of teams:

- ✓ The facility-based quality improvement team(s): members are providers who see patients, they are the ones who have control over the issue identified for improvement, and their performance

directly affects the overall quality of care. They will go through the different steps of a quality effort and will implement the interventions/changes.

- ✓ The quality management team: members are usually the management staff at higher levels, who has authority over the facilities. They must manage the quality effort, focusing on the improvement process, and support the work of quality improvement teams, because they have more control about some aspect of the system of care: finance, regulations, etc.
- ✓ The quality “learning group” is usually made of selected high-level decision-makers who need to be informed of the quality efforts, in order to translate lessons learned on the process and results into national policies, as a Quality Improvement Project (QIP) evolves.
- ✓ Ad-hoc teams might need to be formed as the quality effort progresses, but might not need to last as long as the others. It is difficult to anticipate the need at the beginning of the effort. For example, the pharmacists in a region might be a temporary team needed to address issues with supply of drugs, and disband when they are done, while the other teams continue their work.

For example, In Uzbekistan, the ZdravPlus Project has established 3 types of teams for the management of quality improvement pilot projects in the Ferghana region:

- 3 quality improvement teams are made of providers from all types of facilities (primary healthcare units and hospitals) to address quality issues for patients with hypertension, anemia and childhood diseases. General practitioners and specialists work together with nurses.
- An oblast-level¹³ quality management team is made of all the chief specialists and senior management staff (this staff usually does not see patients).
- A republican working group on quality is made of national heads of clinical care specialties and institutions, the clinical leaders for the topics selected for improvement.

Communicate expectations, objectives and progress on performance to all stakeholders

Many people are involved in the day-to-day operations of a healthcare system, and contribute to its overall performance. Good communication channels are key for effective quality work. This “communication-focus” means several things:

1. Channels of communication must be defined and developed between all involved in the quality activities. It keeps the team together, avoids passive resistance and blockage, and secures commitment. It allows coordination of activities between the different teams and levels of the healthcare system. The team must discuss the ways information is going to be communicated among members.
2. A communication system must be established, with clear identification of who (target audience) needs what (content of the message) information and who (source of communication) delivers it. Information needs vary with people: senior managers just want to know that QI efforts are on-going; financial

¹³ The Oblast is the administrative entity that represents the intermediate management level, between the state/national and the peripheral levels.

managers may want to know only about the impact of QI on cost savings; and clients are just interested in visible results to their health. It is important for the QI teams to identify the information needs of the various stakeholders.

3. *Effective communication involves a behavior change component.* Because we want people to use or react to the information, the way the information is conveyed matters. When designing the communication strategy, the team must include elements of the behavior change theories, such as: using opinion leaders to communicate information, informing a critical mass of people at the same level, explaining the added value of the information and what is expected from the receivers. A communication system cannot be limited to the distribution of information.

In the Ferghana QI projects, several means of communications have been implemented:

- The oblast-level quality management team meets monthly to review the QI projects, using a job-aid developed to facilitate their meeting and decision-making (see *Annex 2*), which is then conveyed to the QI teams by the rayon coordinators.
- The leaders of the quality improvement teams meet weekly at the rayon level, under the rayon coordinator. They analyze the run charts, look at progress, discuss issues and make decisions on interventions and changes.
- A quarterly newsletter, the “*Journey to Quality*” is published to disseminate to all teams some information on the changes that deserve to be replicated and the challenges that remain, as well as informing the republican level on the progress of QI efforts.

Identify, strengthen, build, and sustain leadership in the quality efforts

Many times we hear that something has failed because of “lack of leadership”. While it is easier to expect leadership from someone else, it is also true that quality efforts not supported by “official” leaders do not succeed. This “leadership-focus” means several things:

1. *The leaders of the quality efforts must be identified*, whether their influence comes from their position (authority), their expertise and knowledge (legitimacy) or their own charisma (personality). Leaders cannot be self-proclaimed; others usually identify leaders, by stating who influences them.
2. *Leadership is the capacity to influence* (and lead) others through an attitude, but some level of effective leadership capacity can be built in most persons through training in specific leadership skills.
3. *Leaders’ main responsibility is to build and maintain the ownership* of the team in the quality efforts, to avoid resistance to changes. People usually “resist” changes imposed by someone else or an “external force”, and they need to perceive the quality efforts as their project. Leaders are not managers, but they lead by example in order to facilitate a change.

For example, in the Ferghana QI projects, the chief specialists at the Republican and Oblast levels are involved as members of the various teams, because of their authority and credibility in influencing medical practices in the facilities.

In Short on Improvement Concepts and Quality Management Principles

Three concepts help design an improvement effort:

1. Quality can always be improved
2. No improvement will take place without a change
3. Success comes from learning about the system

Six principles help manage a quality improvement effort:

1. Approach quality from the perspective of the patient
2. Think in terms of systems and focus on processes
3. Base decision on reliable information
4. Make the quality effort a team's responsibility
5. Communicate expectations, objectives and results to all
6. Identify and develop leadership

IV. The Management of a Quality Improvement Pilot Project

Introduction

How do we organize the QI effort so that it runs smoothly, logically and effectively? Quality experts have different ways of translating improvement concepts into concrete implementation approaches. There are several valid reasons for this:

1. ***The management of QI efforts depends very much on the environment and the system in place***, including the dynamic of changes/improvement in a system and the attitude of people working in that system. It is better to flexibly transform principles and concepts into a strategy and action plan that make sense at the time and place where QI takes place, than rigidly apply a standardized approach to every situation¹⁴. The success of a quality improvement effort is influenced by many factors, the method itself might not be the most important as long as it is adapted to an evolving situation (as the quality effort progresses).
2. ***Different organizations have developed various stepwise approaches*** and it is worthwhile knowing them in order to be better equipped. In a way, they represent a “menu” of approaches from which one might want to choose, provided there is a way to predict which one would work best in which environment. Although not one approach could pretend to work in all situations, they all share a common logic. Some of them are derived from previous ones and represent a refinement in the order, number or wording of the steps.
3. ***The capacity to articulate and communicate improvement experiences is limited***, and “forces” us to describe QI efforts as a recipe (whether called a model or a method) with a logical sequence of steps. Such technical approach is easier to explain and teach, but it does not reflect accurately the hundreds of nuances and deviations from the model that will eventually happen when implementers are confronted with field reality. Like clinical guidelines, those methods are a roadmap to guide QI efforts but allow at the same time some flexibility.

While trying to reflect the complex nature of the field of quality improvement, this chapter is also providing some directions for the implementation of a quality improvement effort through a logical sequence of steps, without promoting a unique and prescriptive method. In short, there is no magic in the efforts to improve, replicate and sustain improvements and no “technique” can guarantee results, but following the overall logic and adapting it through common sense increases the chances of success.

Although the term management can be understood very broadly, what we mean is the design/planning, implementation and evaluation of a Quality Improvement Project.

¹⁴ “If all you have is a hammer, everything will look like a nail to you...”

Activities Involved in Designing/Planning a QIP

Before the improvement project can start, one must plan the quality efforts and design its management. Activities at this stage include:

1. ***Getting commitment from leaders*** involved in the healthcare system that one is trying to improve. For example, before we started the QIPs in Ferghana, we met with the managers of the Oblast Health Department and discussed the idea of starting a quality improvement project with focus on clinical care conditions. During the meeting, we had to explain the improvement concepts, the management principles and the overall logic. We also discussed what topics are priority healthcare issues.
2. ***Deciding on the geographic focus*** of the Project. In Ferghana, a consensus emerged that the Project will start in 3 primary healthcare facilities of each one of three rayons (districts), for a total of 9 facilities. At the pilot stage, the team tried to identify a small and manageable number of facilities.
3. ***Setting up a management structure***. This requires identifying who should be in the Project team members and whether different teams would be needed. In Ferghana, we decided to have 2 kinds of teams to start with: managers of the oblast (the quality management team) and providers in each facility (quality improvement teams). The final composition of the team (team members) is usually identified later, once the topic for improvement and objectives are finalized.
4. ***Specifying the roles and responsibilities of each team***. In Ferghana, it was decided that the quality improvement teams would self-monitor their performance against standards, and would be responsible for testing the changes. The quality management team would approve the standards developed by the chief specialists at national and oblast levels, and would support the changes to be tested and replicated.
5. ***Planning the launch of the Project***. This involves setting up the date for the first “step”, which is usually some kind of a workshop or training seminar, during which the providers of the facilities involved will learn what QI means and will start working together. In Ferghana, we trained each team during a 3-day seminar. We tried not to plan too much in advance the details of an implementation plan. Experience showed us that this it is better to go step-by-step and to plan the next steps one at a time. At the end of this first “event”, all participants need to return to their place of work with a clear understanding of their responsibilities and next activities, probably identifying a topic for improvement or narrow it down to a measurable objective.

Activities Involved in Implementing a QIP: the QI Cycle

Many methods have been developed to help manage quality efforts; they all have their names or acronyms¹⁵, and are not always easy to remember. They all bear one thing in common: a logical sequence of steps¹⁶. In particular, we observed that they all include three common “big” steps, even if their names differ: improvement objectives are defined, then interventions/changes are suggested, and finally the changes are tested through small-scale implementation. We give to this continuous process the generic name of the QI cycle.

¹⁵ Rapid cycle improvement, FOCUS-PDCA, team-based problem-solving, etc

¹⁶ The number of steps varies with the method: from 3 to 10.

1. **A team expresses its improvement objective(s)** or the quality issue that it wants to address. At this stage, the team identifies one topic for improvement and narrows it down to a level where the number and types of issues can be expressed in a measurable way (indicators of improvement will be defined). We recommend starting with a clinical care improvement topic, rather than management issues. We also need some reasonable knowledge that the team would be able to do something about it, i.e. it has some control over the system of care. By doing so, a team defines the standards to achieve and what quality means. Main activities under this step usually include, but are not limited to:

- *Know/describe the system to improve*

- ✓ Describe the healthcare system the way it currently operates, through the development of the flow of patients through all the level of facilities (primary level to tertiary reference facility). This way, it takes into account the continuity of care for patients who move from one level of the system to the other and it allows describing healthcare processes at each level (the continuum of care). A flowchart is a useful tool at this stage.
- ✓ Develop a graphic representation of the system, such as a system's view with the usual 3 components (inputs, processes and outcomes), or use a more free-drawing of the components and their interaction, without categorization. Examples of both are provided in **Annex 4**.
- ✓ Identify what happens at each level (the care patients receive) and what we do not know about the care and the information that would be needed.
- ✓ Look for the evidence behind the care (using evidence-based medicine) and make explicit the care patients should receive. This allows finding out the level of performance of the current system and the quality gaps.

- *Identify the QI team members*

As we previously described, different teams might be setup. The composition of the QI team comes from the components of the system to improve and members are the people involved in the various processes of care, both providers and managers.

- *Setup improvement opportunities/objectives*

Improvement goals and objectives come from a consensus of the team on the analysis of the system to improve and the review of existing evidence of the care to be provided. For example, the Maikuduk child health team in Karaganda expressed the following objectives:

Goal: To improve the Quality of the system of care for children <5 in Maikuduk district, with focus on effectiveness of care (patients receive the evidence-based care they need), clinical efficiency (patients do not receive care that has no added value and is a source of waste) and safety (the care does not harm the patient).

Objectives:

- Decrease the mortality of children under five;
- Improve the rational use of healthcare services, especially referrals.

- *Monitor system performance*

A this stage, the team develops its quality or performance monitoring system (see **Chapter VI**)

2. **A team develops ideas for interventions and changes.** Because there is no improvement without changes, the team needs to come up with ideas of changes that it would like to implement, either because they would address the real cause of a problem (problem-solving), hence removing a barrier to improvement, or because they would represent a better system of care (design or redesign of a service/process). At this stage, the team wants to know more about the health system before developing an intervention/solution. Main activities under this step usually include, but are not limited to:

- *Perform a root-cause analysis (RCA).*

This is the time where reasons for poor quality or performance are identified and confirmed. The tools of the RCA process are described in **Chapter VIII**.

- *Identify interventions to remove causes of poor quality.*

Team members generate ideas for changes, with a focus on the main targets for changes: providers, patients, organization of services and policies/regulations (see **Chapter VII** on change management and concepts).

- *Design or redesign a healthcare service.*

In some instances, the number of problems is so high that it is better to redesign a healthcare service from the beginning, starting with patients' needs, rather than trying to fix all problems one at a time. This technique, called quality design (or quality function deployment), requires a high level of technical expertise and assistance.

3. **A team implements interventions/makes changes.** At this stage, the team is implementing an intervention or making changes that address the causes of poor quality/performance. By doing so, the team expects to improve quality, but can only test the impact of the change. Main activities under this step usually include, but are not limited to:

- *Implement the interventions.*

The team uses a tool such as the Plan-Do-Study-Act (PDSA) learning and testing cycle, especially the first 2 steps. At this stage, it also sets up a system to monitor that interventions and changes are being implemented the way they were planned.

- *Analyze the results of the interventions.*

The quality and performance monitoring system established during the first step will help analyze the impact of the changes and interventions on the objectives for improvement. Based on the results, changes will be kept and replicated or modified or discarded.

- *Identify which other levels need to be involved.*

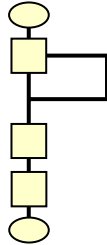
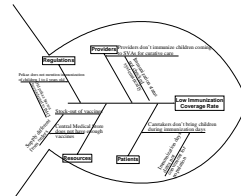

It is not uncommon to find out that interventions under the control of the facility-level team are not sufficient to address all issues, and that higher levels of the system of care need to be involved. This is true for every change needed in regulations or policies, usually under the authority of the central or

national level of the Ministry of Health. It is part of the improvement process to bring the issues to the right forum for discussion and the right level for action.

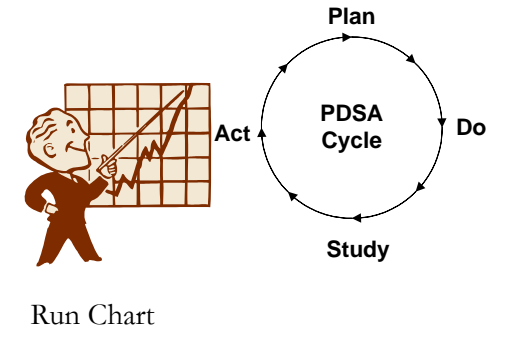
The improvement cycle reflects the iterative nature of QI. It means that a team can repeat improvement cycles on the same topic and the concurrent PDSA cycles for the testing of different changes, or shift to a different topic when the previous one is considered completed. The first cycle could be simplified to allow people to get accustomed to the process by selecting standards of quality that are not too difficult to reach.

Table 2 represents the 3-step logic of our improvement model.

Table 2: The Improvement Model for enhancing Quality & Performance¹⁷

Phase	Questions	Steps	Tools						
Pilot Phase of an Improvement Project	What do we want to improve?	<p>1. Identify the improvement goal and objectives:</p> <ul style="list-style-type: none">• Know/describe the system to improve• Identify the QI team members• Express improvement opportunities & objectives• Monitor system performance	<p>Flowcharting</p>  <p>Systems Analysis</p> <table><tr><th>Inputs</th><th>Processes</th><th>Outcomes</th></tr><tr><td></td><td></td><td></td></tr></table>	Inputs	Processes	Outcomes			
	Inputs	Processes	Outcomes						
	What interventions and changes might lead to improvement?	<p>2. Develop a set of interventions/changes:</p> <ul style="list-style-type: none">• Identify root causes of poor performance• Identify interventions that address root causes• (Re)Design components of the system of care	 <p>Fishbone Diagram</p>  <p>Teamwork</p>						

¹⁷ Adapted from the review of many quality improvement models
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	<p>What interventions/changes were successful?</p>	<p>3. Implement interventions/changes and study their impact:</p> <ul style="list-style-type: none"> • Implement the Plan-Do-Study-Act learning cycle • Measure impact of changes • Identify which other levels need to be involved 	
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Activities Involved in Evaluating a QIP

Once the pilot phase of the quality improvement project is completed, it is important to evaluate it in order to:

- Learn lessons on which aspects of the project worked and which ones did not, both in terms of processes and results (impact on improvement objectives);
- Document and communicate the experience to higher levels of the healthcare system for replication and institutionalization;
- Plan next steps of the project, according to the new knowledge acquired on the conditions needed for success or the reasons for failure.

Activities at this stage might include:

1. ***Organizing a meeting with team members*** to discuss the processes and results, what they liked and not, the lessons they learned and the recommendations they would like to make for the next QI cycle.
2. ***Writing a document*** on the project, which could be either a detailed or short report, or a storyboard, to display the main steps and achievements.
3. ***Performing an in-depth evaluation*** using a mix of qualitative and quantitative research methods to get the perceptions of people involved in the Project, and understanding the factors that affected the results.
4. ***Setting up a visible event***, such as a conference or workshop to present the results of the project to a selected audience.

Annex 5 provides some information on how the quality management principles apply to the various steps of an improvement effort.

In Short on the Pilot Quality Improvement Phase

1. Design and implement a quality improvement effort as a specific project, with clear and measurable targets/objectives, specific interventions and valid measurement of the progress (QI Cycle);
2. Develop clinical care improvement objectives that are supported by evidence-based literature;
3. Establish a quality monitoring system as soon as possible, to measure improvement over time;
4. Because quality is a characteristic of the healthcare system, identify changes to make in that system;
5. Use specific tools and methods to identify quality issues, analyze root-causes of poor quality, and implement changes that could lead to improved quality;
6. Because the impact of changes cannot be predicted, interventions must be rigorously tested;
7. Use quality management principles to manage a quality improvement project;
8. Build and maintain staff motivation and leadership for quality improvement activities;
9. Build support for improvement teams through an enabling and empowering management level;
10. Draw lessons from the improvement project, for replication and sustainability.

V. The Development of Quality of Care Standards

“Standards” is a general term, but the concept behind it is interpreted differently by different healthcare systems: It ranges from “an ideal level of quality” (an objective to achieve over time if conditions allow) to a strict regulation (a law not to violate). The amount of variation from the standards that is acceptable, i.e. accepted, varies across systems. Some systems are more rigid and do not tolerate (and even repress) any deviation from explicit standards of care, while other systems consider that standards are just necessary to guide clinical decision but can be interpreted differently, as long as providers can explain the reasons for non-compliance. When they are enforced too rigidly, standards of care might even be detrimental to the quality of care if the provider ignores specific circumstances for which the standards were developed. Diseases do not always present exactly the way they are described in medical books and associated health conditions may require justified deviations from the standards defined in a guideline that addresses only one condition.

In this chapter, we will try to clarify the role of standards in a quality improvement effort.

Why we need Standards

One important activity of a quality improvement effort is to define quality. This is done by expressing what providers should do (for example, provider checks danger signs for every child with high fever; this is the process of care), the immediate result of this action for the patient (for example, children with danger signs are referred to a hospital; this is an output of the care) or the overall impact on health (children with severe pneumonia are cured; this is an outcome). Because they explicitly describe the expected level of performance in the delivery of healthcare, these statements are standards.

Standards of clinical practice describe what care is more effective in particular circumstances, how the care should be delivered (processes), and what results (outcomes) can be expected. Standards can be presented under different formats (guidelines, protocols, etc.) and focus on different aspects (resources, processes, results) of a system. Standards can also be developed for the organizational aspects of the healthcare system (administration and management of the care) and are not limited to the clinical content of the care. In fact, because they express expectations, standards can be expressed for every component of the healthcare system.

Standards are needed because:

- They ensure public safety. For example, standards define the maximum amount of particles per mm of water that is allowed in order to avoid contamination of drinking water and epidemics.
- They establish the right for a health facility to operate. For example, accreditation of hospitals is mandatory or strongly recommended in certain countries, and their right to deliver care depends on their meeting many standards.
- They state the level of expertise of providers. For example, the licensing and certification of physicians requires, in many countries, to pass a test and attend certain hours of continuous medical education per year.
- They inform providers of the acceptable level of care. For example, many guidelines and protocols described the latest knowledge in evidence-based medicine.
- They limit the risks of harm to patients. For example, standards for risk management include the care that immobilized patients should receive so as to avoid phlebitis and pulmonary embolism.

- They specify what technology should be used in what circumstances. For example, the field of health technology assessment studies the cost-effectiveness and impact of different technologies for the treatment of health conditions.

Because standards do all of the above, they contribute to maintaining and improving quality of care, limiting harmful variation in the delivery of care and enforcing public accountability of providers and the entire healthcare system.

There are basically three types of standards most useful for a QI effort, depending on which aspect of the system they focus: inputs, processes and outcomes.

- The health system inputs include all physical and financial resources such as health personnel, hospitals, laboratories, instruments, equipment, drugs, budget, and so on; i.e. all physical items and people necessary to deliver care.
- Health care processes are particular set of actions intended to achieve a result; for example, an operation or a treatment or the process of inserting a catheter.
- Health system outcomes represent the results achieved. They could be broad (overall mortality in a country or birth rates in a region) or more specific (for example, number of hypertensive patients whose blood pressure was normalized in the past month).

Table 3 gives an example of the three types of standards of care related to a specific episode.

Table 3: Example of Inputs, Processes, Outcome Standards

A patient was brought by ambulance to the hospital. After physical examination, lab exams, and X-ray, the patient was diagnosed with acute appendicitis. A surgical team performed an operation to remove his appendix under general anesthesia. Patient was given antibiotics to prevent infection. The physician followed him daily. After 4 days, the patient was discharged from the hospital without complications.

Input standards might include policies and regulations regarding how many staff with what qualifications should be on site each day to address emergency calls; what type of ambulance with specified list of instruments and equipment should be available; what types of physicians and diagnostic equipment should be present at the hospital; what type of drugs should be in stock at the hospital, etc.

Process of care standards include information on what type of first aid should an emergency team provide; what are the criteria for transportation to a hospital; what diagnostic procedures should a patient with symptoms of acute abdomen undergo in the hospital; what are the surgical methods to be used; what drugs should be administered; criteria for discharge; what is the follow up care, etc.

Outcome standard is the successful treatment of the cases, as measured through complete recovery without complications, such as post-surgery infection rate.

The definition of clinical standards of care has become less controversial since methods exist to analyze systematically the results of scientific research and to derive, from the findings, clinical practice recommendations. These methods promote the practice of a medicine that is based more on science than art, called evidence-based medicine.

Evidence-Based Medicine

Medicine is a fast growing and changing scientific field. The medicine that senior physicians are practicing now is different from the one they were taught at the medical school 20 years ago: new drugs have been developed (for example, new antibiotics or antihypertensive drugs that are more effective and have less side effects), new technological discoveries are made (for example, which allow for microsurgeries instead of more invasive operations), and new protocols are developed, which sometimes advocate for less treatment procedures. New knowledge is growing exponentially. Between 1966 and 1995 only about 85,000 randomized clinical trials were published. More than half of all scientific articles have been published in the past 10 years.

It is a challenge for medical practitioners to keep their knowledge up to date and translate this knowledge into immediate practice for the benefit of their patients. This issue is even more acute in working conditions with poor access to information (no internet, no subscription to modern literature), like in rural areas or low-income countries with a developing economy. Many surveys have revealed and quantified wide gaps (and sometimes a real chiasm¹⁸) between what care should be delivered and what happens in reality. A large body of evidence has been accumulated on unacceptable and unjustified variations in clinical practice and performance among healthcare providers and facilities:

- Similar patients in similar circumstances are being treated differently and experience different outcomes;
- Many patients keep receiving care that has no added value and is not based on evidence, leading to unnecessary increase in costs;
- Many patients are harmed by unsafe care, leading to excess morbidity and mortality¹⁹.

Evidence-based medicine is the conscientious, explicit and judicious use of currently available knowledge (the evidence) for making decisions about the care of individual patients. The practice of evidence-based medicine means *integrating providers' clinical expertise with the best available external clinical evidence from systematic research* (D. Sackett BMJ, 1996, 312, pp.72-3). In other words, a modern physician must use both his clinical knowledge & judgment and the best available external evidence, and neither one alone is sufficient. Without the use of sound judgment, a clinical practice guideline might be inapplicable or inappropriate for a specific patient. Without knowledge of available evidence, clinical practice becomes rapidly out of date, to the detriment of patients and patient-care. External clinical evidence is designed to inform, but can never replace individual clinical expertise that decides whether the external evidence applies to the individual patient at all and, if so, how it should be integrated into a clinical decision.

If, as suggested above, clinical care standards are based on the best available evidence then it is logical to conclude that standards are not norms to be rigidly enforced, but rather a recommendation or a guide for the health providers who can justify reasons for both use of, and deviation from, the standard.

In practice, the technique of evidence-based medicine consists of reviewing the research published on a specific topic/health condition, assessing the validity of the findings, and rating the strength of the evidence for each finding on health outcomes. These findings are then used to make recommendations to providers about the care to patients, and these recommendations are published under different formats: long clinical

¹⁸ *Crossing the Quality Chasm: A New Health System for the 21st Century*. Committee on Quality of Health Care in America, Institute of Medicine. Washington, DC, USA: National Academy Press; 2001

¹⁹ *To Err Is Human: Building a Safer Health System*. Kohn LT, Corrigan JM, Donaldson MS, eds. (Committee on Quality of Health Care in America, Institute of Medicine). Washington, DC, USA: National Academy Press; 1999

practice guidelines, short protocols, clinical pathways, etc. Evidence-based medicine is considered to better promote quality of care because recommendations are based on rigorously analyzed facts and not only on experts' opinions. Methods for both original clinical research studies and systematic reviews of published articles come from the fields of epidemiology and biostatistics.

Because the results of individual studies are sometimes inconclusive or contradictory, scientists developed a scale for grading the strength of the evidence, depending on the design of the study that produced these results. The scale is presented by order of decreasing evidence, from the strongest to the weakest:

- I a – evidence from meta-analysis of randomized controlled trials
- I b – evidence from at least one randomized controlled trial
- II a – evidence from at least one controlled study without randomization
- II b – evidence from at least one other type of quasi-experimental study
- III – evidence from non-experimental descriptive studies, such as comparative studies, correlation studies, and case-control studies
- IV – evidence from expert committee reports or opinions or clinical experience of respected authorities, or both

Based on the review of the evidence, clinical recommendations are classified according to 4 levels of evidence, which define the strength of the recommendation:

- A-directly based on category I evidence
- B-directly based on category II evidence or extrapolated recommendation from category I evidence
- C-directly based on category III evidence or extrapolated recommendation from category I or II evidence
- D-directly based on category IV evidence or extrapolated recommendation from category I, II or III evidence

A specific tool, AGREE²⁰ (Appraisal of Guidelines, Research and Evaluation) grid, has been developed by 11 countries to help experts assess the validity of guidelines, based on compliance with the EBM process.

The Formats and Types of Clinical Standards

Clinical standards describe recommended care and expected clinical performance. They come in different formats, because they respond to different needs and target different healthcare providers. There is no universal agreement on the names of different formats for clinical standards and the literature is confusing. Professionals in different countries or different organizations use various terms interchangeably to describe the same format for clinical standards. The following is an attempt to clarify the basic differences between the various terms:

- **Clinical practice guidelines (CPG)** – usually describe in detail examination, diagnostic, treatment and follow up steps for a specific condition/disease. Mostly used by physicians to guide them in providing appropriate care. Depending on the health condition, they are usually rather long documents

²⁰ Website: www.agreecollaboration.org

(40 to 50 pages and more), providing details on the evidence behind the recommendations, as well as indicators of monitoring for its implementation.

- **Algorithms** – usually a very short schematic representation of procedures (such as a flowchart or decision tree), often used in emergency care departments and urgent situations requiring immediate actions;
- **Clinical pathways** – usually provide day-by-day schematic representation of standardized care, often designed for and used by nurses;
- **Procedures** – usually provide a step-by-step instruction of how to perform a medical task (for ex. insertion of an urethral catheter);
- **Protocols** – usually describe the case-management of a patient with a very specific condition, in a short document. A protocol could be compared to the summary of a CPG.

Because they respond to different needs for the same patient, different formats might be useful for the management of the same health condition at different times of the healthcare delivery process and for use by different personnel. An example of such a “system” of standards is provided in *Table 4*.

Table 4: Example of different types of clinical standards that respond to the needs of various personnel and contribute each to the quality of care for Cesarean Section *

The **administrative policy** reads: “Cesarean sections may be performed by physicians credentialed in surgical **procedures**, both general surgeons and obstetricians. An operating room within the general surgery will be designated and equipped for the management of cesarean sections. If the obstetrical suite is occupied, a general surgery suite may be used. Patients who require invasive monitoring or intensive care management will be referred and transported immediately to X Regional Hospital and accompanied by a physician or obstetrical nurse.”

Clinical practice guidelines regarding “Practice guidelines for obstetrical anesthesia”; “Prevention, diagnosis, and treatment of failure to progress in obstetric labor”; and “Elective repeat cesarean section” were used to guide medical practice.

A **clinical pathway** for the normal post-operation care management was developed for the nurses.

Algorithms were developed for the emergency management of pre-eclampsia, eclampsia, and fetal distress in conjunction with the physician’s standing orders. The algorithms provided a quick visual diagram of how to treat the patient based on the presenting signs and symptoms. These algorithms were posted on the walls of the consultation rooms.

The team was also using **protocols** for prevention and management of phlebitis and a protocol for patient and family education.

*Adapted from “Taxonomy of Health System Standards” by Joanne Ashton, QAP 2000.

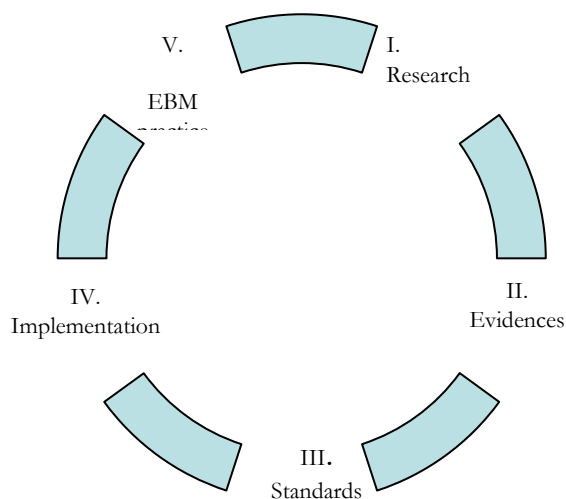
The development of different “documents” on standards of care is a relatively recent phenomenon and requires healthcare providers to integrate these “tools” in their daily practice. Whereas nurses are used to clinical care maps, most physicians find it difficult to use CPGs and protocols while delivering the care. Since memorizing these documents would be an impossible task, the idea came of extracting from them a one-page algorithm that could be used as a job-aid during a consultation. The objective is to make available reminders to physicians. These reminders have proved to be very effective to limit variation and increase reliability in the care being delivered, but the real challenge is to educate providers to be willing to use these tools.

Standards Development Process

As mentioned, standards are tools used by healthcare professionals to assist in clinical or managerial decision-making and to improve healthcare for patients. The concept of recommendations providing guidance is not new. For many years clinicians have used treatment recommendations, immunization schedules, textbooks and practice bulletins to guide their practice. However, traditionally, guidelines have been based on consensus among experts. This process has its limitations as it usually only includes some but not all perspectives and can lead to flawed conclusions. Expert opinion does not always reflect the state of current knowledge. Furthermore, it is necessary for research literature to be analyzed systematically in order to avoid biased conclusions. The difference over the last decade has been the increasing focus on systematically summarizing evidence from research studies in order to develop more valid recommendations.

The transformation of research findings into medical practices is a continuous process that follows the cycle represented in the figure below.

- I. Researchers conduct scientific investigations on specific topics (for example, to determine the effect of hypertension treatment on stroke prevention) and the results are published in the scientific literature (medical peer-review journals).
- II. The results of different studies on the same topic are reviewed and summarized, using a technique called meta-analysis.
- III. Expert teams develop clinical practice recommendations based on evidences from scientific literature, and publish them in appropriate formats.
- IV. Standards are made available, tested and implemented into the medical community.
- V. Health workers practice evidence-based medicine.



Developing, updating and implementing evidence-based clinical standards of care involves a number of generic steps that could be summarized as follows²¹:

²¹ Adapted from the Scottish Intercollegiate Guidelines Network (SIGN), one of the best known and most respected guidelines development groups

1. The first step is to **select and prioritize guidelines for revision**, taking into account morbidity, mortality, and cost data. Conditions having the greatest negative impact on health status should ordinarily be given highest priority as well as conditions for which greater improvements can be expected.
2. The next step is to **establish the guidelines development group**, made of many different stakeholders. Specialists trained in EBM critically assess the scientific literature. Clinical specialists and generalists who will be using the guidelines need to foresee problems with implementation and identify ways to avoid or minimize them. Experts in health care planning and policy issues must be involved in cost-effectiveness analysis. Actual patients and/or representatives of patient support organizations should be full members and provide input, particularly regarding implementation.
3. Once formed, the team's first task is to **perform a systematic review of the literature**. This requires searching for existing evidence-based guidelines, meta-analyses, and systematic reviews and selecting reports that meet agreed-upon criteria. When appropriate, randomized clinical trials (RCTs), observational studies, and other research reports should also be considered.
4. After all members of the group have thoroughly studied this evidence, the team should meet to discuss its consistency, weight, and generalizability. The group is then ready to **formulate its recommendations**. As it does so, it should grade each recommendation based on the strength of the evidence available.
5. Before the new guideline is implemented, there should be a period of **consultation and peer review**. SIGN recommends that the draft guideline be presented at an open National Meeting. Useful feedback is incorporated and the revised guideline is submitted to the Commissioning Body. A final draft of the guideline is then prepared.
6. When both the development team and the Commissioning Body have approved the final draft, the new guideline is ready for **implementation**. Ideally, regional workshops are held and a "Users Guide" (for clinicians) and "Patient Information" booklets are disseminated.
7. Finally, a **formal review** of the new guideline should be scheduled.

Many professional groups (West Europe, USA, New Zealand) develop standards for specific diseases/conditions through reviewing all existing literature. These standards could serve as a basis for other countries that can validate and adapt them to their local conditions. Another opportunity is to use already systematized material by professional groups such as Cochrane collaboration that bi-yearly publishes a summary of all most recent evidences (also available on CD).

Standards Implementation Process

Once standards are developed it is essential to effectively implement them in the medical practice (implementation strategies ideally should be thought out even before the standards are developed). It is often assumed that once standards are distributed and regulations²² to enforce their use are issued, it is enough to make health workers change their medical practices. Many studies demonstrated that this strategy is not sufficient to address issues of practitioners' resistance to change or to remove the barriers to implementation that are related to the organization of the entire healthcare system.

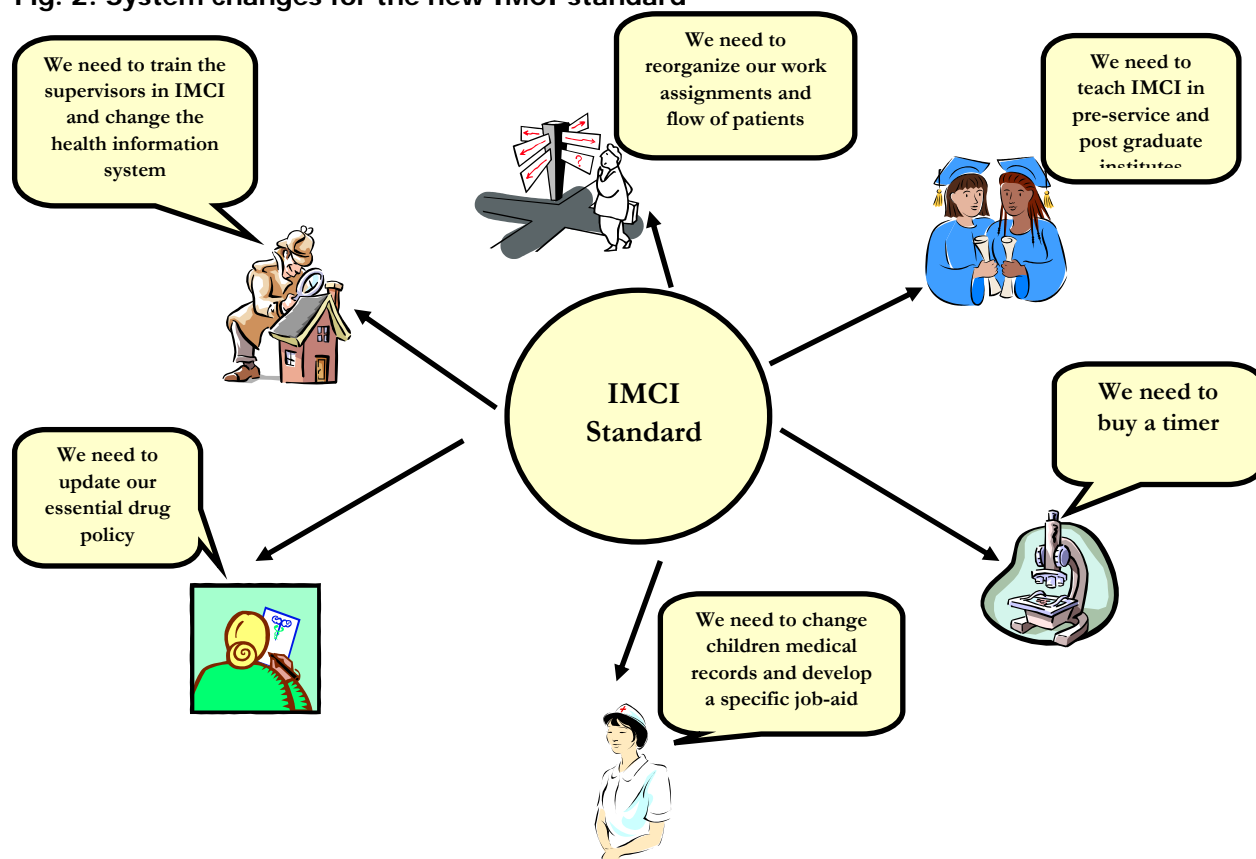
Health personnel experience many challenges in implementing the new standards. The three most common challenges are:

- Health workers are reluctant to implement standards that question their current medical practice and require a significant behavior change. Many physicians, especially with many years of practice, do not understand the principle of EBM and the idea of changing their practice. They strongly believe that personal experience is stronger than research and evidence. For example, many practitioners do not really perceive the added value of a new guideline recently introduced in Central Asia for the management of childhood diseases: IMCI²³.
- Health workers receive the standards without the training to implement the new standard. It is often the situation when there is no explanation/training provided. For example, the IMCI guideline requires an 11-day training course, is quite expensive, and the total costs of the program to cover a huge workforce is usually beyond the funds available.
- The system does not allow health workers to implement the new standard. For example, the guideline recommends a drug that is not available in the market or is too expensive for the general population. Standards developers need to bear in mind that the system of care will need to be adapted/changed in order for the new standard to be feasible: services might need some reorganization, equipment and drugs should be revised, monitoring and supervision teams need to be informed of changes, reporting forms should be adapted, education or training institutions should introduce the new standard into their curriculum, etc. *Figure 2* illustrates potential changes needed for the successful introduction of IMCI, beyond just training the providers.

²² Such as prikazes, those regulations issued by Ministry of Health in former Soviet Union countries

²³ The Integrated Management of Childhood Diseases (IMCI) is an integrated approach to assess, classify and treat the most common conditions responsible for the morbidity and mortality of children under-five in developing countries.

Fig. 2: System changes for the new IMCI standard



These challenges in the implementation of standards can be met through different interventions, but not one guarantees full implementation and a more effective strategy will include several components. Among those components, five should be considered:

1. Information that a new guideline exists; The information about the new guidelines can be spread using existing communication channels, such as medical journals, bulletins of professional associations, or the Ministry of Health own procedures.
2. Development of providers' knowledge and skills to implement the new practices; Teams of providers can be introduced to the new guidelines at the oblast and rayon levels, through short knowledge-based workshops and longer performance-based training sessions, when necessary. Professional associations have a key role to play in the training.
3. Integration of the new materials into the medical education system, both undergraduates and post-graduates and the continuous medical education system.
4. Implementation of QI projects aiming at setting the conditions for the implementation of the new standard. This includes the self-assessment of providers' performance against the new standards. The identification and implementation of system changes is the focus of a chapter in this document.

5. It is unlikely that the information on and training in the new standards will be sufficient for the new medical practices to be implemented. International experience in implementing new standards reveals that better results are obtained when the communication strategy is supplemented by a behavior change strategy that includes:

- Political support from the leaders (chief specialists) in implementing the new practices, including the removal of punishment for not practicing the old way (structural factors for change);
- Peer-support for the new practice. For example, a critical mass needs to know and be trained about the new practice (relational factors of change);
- Individual factors, such as explaining the intrinsic benefits for following the new guidelines and protocols, including: economic incentives, benefits for the patients and related providers' satisfaction.

In short on EBM & Standards

Evidence-Based Medicine is a modern and relatively recent technique to review the results of international research on diseases and their treatment, and transform them into clinical practice recommendations that would provide the maximum benefits for patients. It complements the clinical experience and “clinical sense” that practitioners have acquired, by helping them to make better decisions. The philosophy behind EBM is that providers should not prescribe care for which the benefit has not been demonstrated by scientific evidence or for which evidence of harm exists.

Standards of care can take different formats because they respond to specific needs of various audiences. In order to contribute best to a quality improvement efforts, most standards should not be enforced rigidly.

VI. The Measurement of Quality

The measurement of quality requires i) *developing indicators* (measuring compliance w/standards of care or achievement of improvement goals), ii) *setting up a quality monitoring system* (data collection tools and a strategy), and iii) *interpreting variation* (transform data on performance over time into information) to answer the fundamental question of an improvement effort: is quality improving?

Why we need to Measure Quality

Without measurement, we won't know if quality of care is improving and if the interventions and changes that we implement produce the expected effect. In fact, setting up a quality measurement system is one of the first tasks of a quality improvement team, once the improvement goal has been defined. Three types of indicators can be measured, but not all need to be systematically included:

1. **Outcome/impact indicators** that reflect the overall performance of the system that is the target for improvement, as the end-result of the QI project;
2. **Intermediate indicators** (could be inputs, process or outcomes indicators) that represent achievement of the improvement objectives specific to one component of the system to improve; and
3. **Indicators of implementation** of the interventions and changes being tested (usually an output of the improvement effort). Without them it is quite difficult to interpret variation in the other indicators.

For example, the Child Health Improvement project in Maikuduk, Kazakhstan, developed indicators presented in *Table 5*. In this project, the oblast team wanted to improve child health outcomes and use of services, through interventions at the primary care level, at the ambulance transportation system and at the reference hospital.

Table 5: Quality Measurement System for the Child Health Improvement Project in Maikuduk

Indicators of Performance of the Overall System of Care for Children	Intermediate Indicators of Performance/Quality	Indicators of Implementation of Interventions/Changes
Mortality: Overall under-five mortality rate of Maikuduk district Primary causes of mortality 0-1 year and 1-5 years Use of Services: Rate of self-referrals to the 2 hospitals % of parents who called the ambulance during day time for non-severe pneumonia or diarrhea	At Hospital Level: Rate of appropriate admissions for ARI and diarrhea Median length of stay for pneumonia and diarrhea Lethality rates for pneumonia and diarrhea	At Hospital Level: Development of admission criteria for ARI and diarrhea Development/availability of evidence-based treatment protocols Proportion of children treated in ambulatory
	At Ambulance Level: Use of IMCI guidelines for children 1 week-5 years old Compliance with IMCI guidelines Appropriate referrals/transport to hospitals	At Ambulance Level: Proportion of ambulance doctors trained in IMCI Development of an ambulance call management checklist
	At the Primary Health Care Facility Level: Use of IMCI guidelines for children 1week-5 years old Compliance with IMCI guidelines Appropriate referrals to hospitals	At the Primary Health Care Facility Level: Assignment of additional health providers Proportion of doctors trained in IMCI Procurement of IMCI stamps

Developing Indicators of Quality

An indicator of quality is a measure that can be used to determine the level of performance of a system or process, the degree of adherence to a standard or the achievements of a quality goal. Good indicators of quality are:

- **Reliable:** Using the same process to calculate the indicator will produce the same result;
- **Objective:** The indicator is understood the same way by everyone and not subject to different interpretation over time;
- **Sensitive to change:** A small change in the system of care will immediately induce a variation in the indicator;
- **Easy to calculate:** The level of effort is feasible and not a disincentive for monitoring;
- **Relevant:** The indicator measures what the team wants to achieve and refers to a standard supported by evidence.

When developing indicators of quality, there are 3 basic rules to remember:

1. If quality has been defined through standards of care, then ***measuring quality means assessing the level of compliance with those standards***. When standards are explicit, it is easier to identify indicators. If teams struggle with the development of indicators, it is often because the improvement objectives are not clear. For example, if the objective is to improve the treatment of patients with diabetes, then the indicator will measure how often this is happening, i.e. the proportion of patients whose blood sugar is within the normal range.
2. ***Indicators of quality focus on processes and outcomes***. One needs to balance the type of indicators between different categories of standards. Whereas outcome/impact indicators might be “good enough” to reflect the overall performance of the health care system, they might not always reflect the inherent quality of the care, which is better captured through process indicators. The reasons for including process indicators are the following:
 - Patients might receive effective care, but at a tremendous cost for the system because most efficient drugs or procedures were not selected despite being as effective (the use of generic drugs instead of brand names is a good example of increased efficiency).
 - Many patients still receive care that is not needed, in addition to receiving the effective care that is responsible for their cure. This is a deceiving situation, where improvement opportunities and quality of care issues might be hidden. Wasteful cares might still end-up in patients feeling better, and whose natural course of the disease (or just pure luck) prevented them to suffer bad outcomes from useless and potentially dangerous exams, procedures and treatment (non based on evidence).
3. ***There are no universal indicators of quality***. In a specific situation, indicators will always be the result of a consensus among members of a team, and they will be easier to develop when the improvement goal is clearly defined. Group discussions on the choice of indicators can be endless and scientific methods to assess their feasibility and reliability exist²⁴ but are resource-intensive because they require validation through testing. This is more appropriate for an entire health information system, but not practical for a facility-based team aiming at rapid improvements.

In Ferghana, the QI team developed indicators directly from the process and outcome standards that had been defined as objectives for improvement. *Table 6* reflects the logic of the team, where standards were made explicit for each step on the continuum of care (from screening to follow-up) and process of care indicators measured providers’ compliance with standards, while outcome indicators reflected the benefit for the patient.

²⁴ The RAND Appropriateness method combines scientific evidence and expert opinion.

Table 6: Example of input, process and outcome indicators for iron-deficiency anemia

Continuum of Care	Standard	Indicator	Comments
Screening for anemia, and confirming the diagnosis and severity	A health worker measures Hb level of patients ²⁵ according to laboratory standards, if they fall into one of these categories: <ul style="list-style-type: none"> • First visit to a health facility • First pre-natal care visit • Annual preventive visit • Symptoms and/or signs of anemia 	Out of all patients who received the test how many were diagnosed with anemia based on the Hb level as recorded on medical card	This is an <u>outcome indicator</u> , since it reflects the result of the screening system performed according to the standard.
Decision on treatment and referral	When referral criteria are not met the physician treats the patient in ambulatory by prescribing 120mg per day of elementary iron and 400mcg folic acid for at least 3 months until normalization of Hb, and 60mg of elementary iron per week for another 7 months	Out of all patients with anemia how many were prescribed an appropriate treatment	This is a <u>process indicator</u> . It will show if there are any gaps in prescription practice of the physicians.
Counseling of the patients on management of anemia	All providers must be trained in counseling on rational nutrition to prevent iron-deficiency anemia	Out of all providers, how many have been trained in counseling for anemia	This is an <u>input indicator</u> . It tells us if the standards of resources are met, and can potentially explain why counseling is not provided

Some organizations use a set of 4 types of indicators as the basis to assess quality of care. This set reflects various dimensions and perspectives on quality, usually: i) the effectiveness of care (outcomes indicators: was the patient cured? Did the care have the intended effect?); ii) the efficiency of care (cost of care per patient, savings: was the care delivered with the most efficient use of resources?); iii) the process of care (compliance with clinical practice guidelines: was the care delivered based on scientific evidence?); iv) the opinion of patients on the care they received (satisfaction: was the patient happy with the care and what are areas for improvement?). These 4 aspects usually reflect adequately the improved performance of the healthcare system. **Figure 3** is an example of such a monitoring system with its application to the care of patients with hypertension.

In the process of selecting indicators, the following points must be considered:

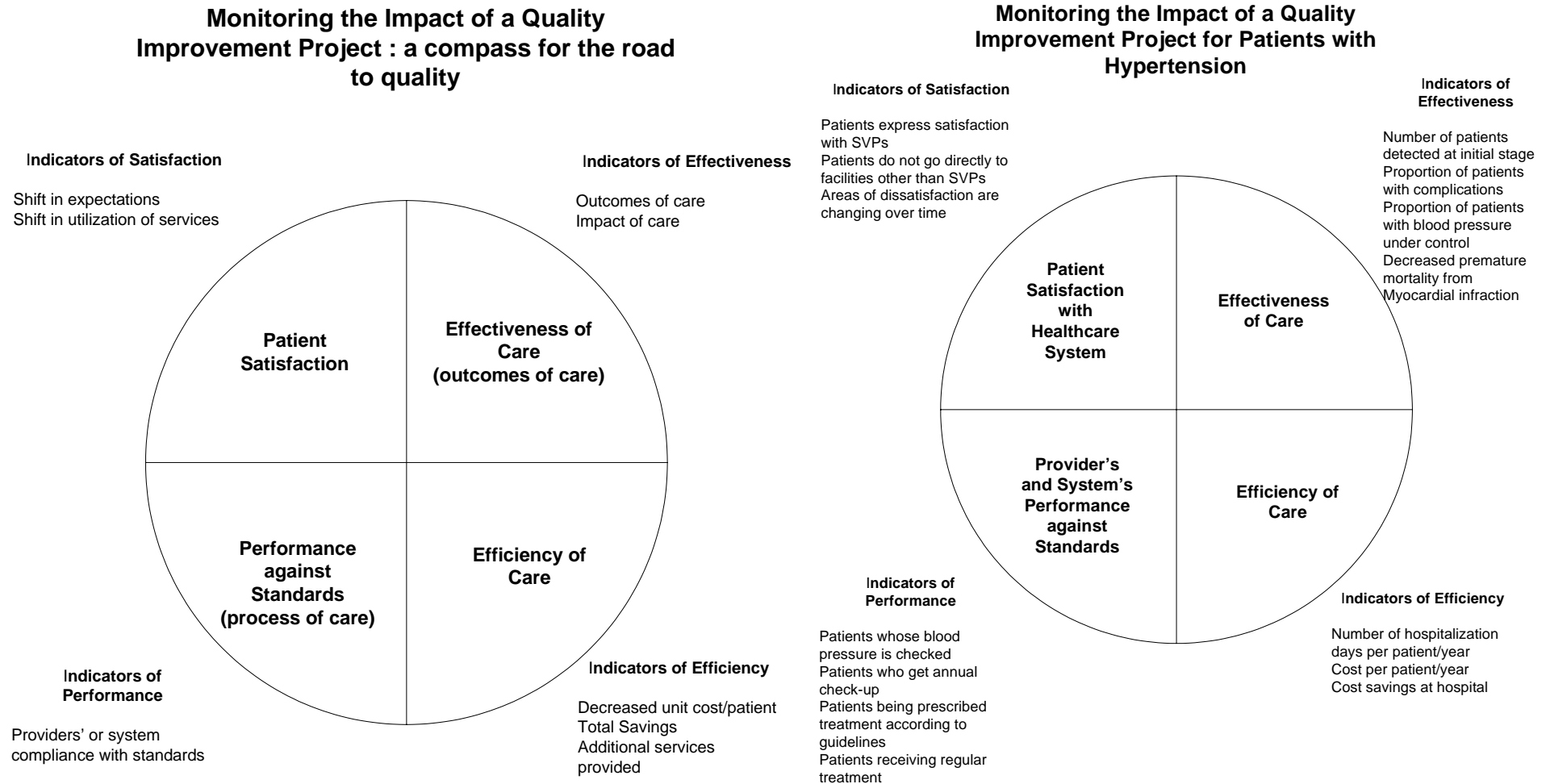
- The indicator is very often a ratio. When this is the case, both numerator and denominator need to be very explicitly written, especially because the source of information might be different.
- Inputs indicators have some value in providing information on potential causes of poor quality, but they are rarely sufficient to provide relevant information on the quality of care itself. For example, the fact that a facility possesses only one blood pressure machine for 5 physicians might be a cause for 50% of patients not being properly diagnosed with hypertension, but does not in itself indicate that blood pressure is not being checked.
- It is not realistic to measure indicators of compliance with each and every task that a provider must perform. The number of standards can be phenomenal if one considers all possible situations/decision-making points in a clinical care guideline or piece of advice a patient should

²⁵ The word “patient” throughout this document refers to pregnant and non-pregnant women between the ages 15 and 49 unless specified otherwise.

receive. Hence, we want to select the process indicators that are the most “important”. Some tasks are more important than others if they help select the best course of action among many alternatives, i.e. a decision-making point. For example, counting the respiratory rate for a child with a cough or difficult breathing will help differentiate a pneumonia (for which the child needs antibiotics) and upper respiratory infection (for which an antibiotic would be ineffective and inefficient). A lot of personal judgment and team consensus will be needed when selecting indicators.

- The improvement trend must be unequivocal. We want to avoid ambiguous indicators such as “decreased referrals to hospitals”. A change in this indicator might or might not correspond to an improvement, depending on the motives for referrals. It is better to measure whether referrals are appropriate, i.e. patients are referred according to explicit and justified criteria.

Figure 3: Example of a Quality Monitoring Compass, adapted to the care to Patients with Hypertension



Setting up a Quality Monitoring System

Monitoring is the routine collection and review of data to assess whether the process of care is being followed and whether the outcomes have improved. Through monitoring, managers, supervisors and health workers themselves can determine whether the services delivered follow the recommended practice set in the standard and achieve the desired results. A reliable monitoring system is crucial in an effort to improve the quality of care.

Steps to follow to set up a monitoring system, once indicators have been identified, include:

1. **Selecting data sources.** Data to compute the indicators can either be found in existing databases (such as the health information system and statistical reports) or will require designing specific data collection forms. Although health facilities sometimes collect a lot of information, it does not mean that this information is relevant to quality of care and that the data needed is easily available. A frequent source of information on clinical processes of care is the patient's medical record. Chart review is the most common data collection strategy, but is limited by the type and amount of information that providers record. Because monitoring is a routine exercise additional data collection should be minimized.

In Ferghana quality improvement projects, specific data collection forms were designed to facilitate the identification of sources of data, as well as the standardization of data collection processes. These forms provide all the information necessary to describe the indicator, understand its processing and its use for decision-making. An example of such a form is provided in *Annex 3*.

2. **Designing a data collection process.** The system for collecting data requires establishing the frequency of data collection, identifying the data collection method, and defining who will collect and compile the data. This process should involve the members of the quality improvement teams. During the initial phase, health workers will need assistance in collecting data and testing the new monitoring system. Many alternative methods exist to collect data on quality of care, and the main ones are summarized in *Table 7*.

Table 7: Data Collection Methods for a Quality Monitoring System

Methods	Description	Main advantages	Main disadvantages
Direct observation of providers	Someone (a supervisor or a colleague) observes the process of care during a medical visit and provides advice/comments for improvement	Very informative of the clinical performance of an individual health worker	<ul style="list-style-type: none"> • Time consuming • Influences the performance of the providers and does not always reflect reality
Medical audit	Someone reviews a representative sample of medical records to answer specific questions.	Easy and not too time/resources consuming	<ul style="list-style-type: none"> • Depends on the type and quality of the information recorded in the medical record
Exit interview of patients	Someone interviews clients when they exit the clinic. The questions look for objective facts (what did the provider do? What care did you receive?) and more subjective information (how satisfied are you with the care?)	Captures clients' perspective on quality and reasons for dissatisfaction	<ul style="list-style-type: none"> • Time/Resource consuming • Depends on clients' willingness to be open and memory of events • Courtesy bias, when patients try to please the interviewer
Interview of providers	Someone asks questions to the providers on clinical care processes in a specific situation	Tests the knowledge of the provider	<ul style="list-style-type: none"> • Does not always reflect what the provider does in reality
The mystery patient (or surrogate)	A patient is trained to mimic a disease (complaints, and symptoms) and observe what the providers do. The interviewer debriefs the patient after.	Avoids the observation bias	<ul style="list-style-type: none"> • Ethically questionable • Resource intensive

A more strategic dimension of the data collection system depends on who collects the data and their relationship with the people whose performance is being assessed. *Table 8* presents the main alternatives for data collection.

Table 8: Data Collection Strategies for a Quality Monitoring System

External assessment	Usually means a supervisor's visit or anybody external to the health facility team	When properly done, provides objective information	Depends on the objectivity and intentions of the observer. If fault-finding, could be detrimental to the improvement project
Self-assessment	Health workers assess their own performance	Promotes ownership and motivation in the improvement effort	Risk of bias and hiding of problems Requires some "external" quality control

In Ferghana QI projects, self-assessment of quality was selected as the method of choice because it was important to build the trust between the QI teams and the management level, as well as disconnecting this effort from the usual blame and punishment that inspection visits focus on. This self-assessment is more appropriate when providers know what is wrong or what could be improved in their work, and motivates them to identify and implement solutions.

When a supervisor acts more as a colleague or mentor than an inspector, external assessment can be very valuable by using the visit not only for assessing quality but also addressing issues and solving problems, based on the trust relationship that exists.

3. ***Controlling the quality of data.*** The quality assurance (QA) of the data being collected is very important, especially when the quality monitoring system is being setup, because there are many opportunities to make mistakes. A specific QA system must be set up where an external staff who masters the monitoring system can check on a sample of cases that the correct data is being collected. This allows testing the feasibility and accuracy of the monitoring system and adapting the data collection forms as needed.

In Ferghana, the QI specialist providing technical assistance to teams observed the data collection process at facility level, and reviewed the accuracy of the data collected on a sample of medical records. This allowed identifying the sources of errors, to better explain the process and to eliminate indicators that were too unreliable. Based on this information, the monitoring forms were redesigned.

Interpreting Data and Understanding Variation

The purpose of interpreting data is to extract information needed to make decisions. Getting information from data is not always as easy as it might seem, because it requires understanding the concept of variation and interpreting changes in data over time.

Variation is a natural phenomenon. There is always variation in data, whether the data measures daily changes in temperature or the success of a surgical procedure. Variation in data does not always mean that quality improved or changed. In the early twentieth century, Walter Shewhart developed the concept that variation should be viewed in one of two ways:

1. Variation indicating that something has changed (indicating that quality is better or not), due to a special cause. This is called special cause variation and indicates that something has changed in the system producing this performance; and

2. Random fluctuation that continues over time and does not indicate that a particular change has occurred. This is called random or common cause variation, and it indicates that nothing has changed in the system that is producing this performance.

The objective of interpreting data is to distinguish between common-cause and special cause variation. Understanding the nature of the variation is paramount in decision-making about improvement efforts. For that, data must be plotted over time in order to detect a pattern that indicates either a real change in quality/performance or normal variation in performance of the same system. The technique of plotting data over time can be accomplished by drawing a run chart.

A run chart (sometimes termed a time plot) can assist in understanding variation and is used to examine data for trends or other patterns that occur over time. It graphically depicts the history and pattern of variation in an indicator or measure. Plotting data regularly on a graph shows when shifts and changes occur and can help identify if and when problems appear. The run chart is one of a number of tools that is useful for:

- Understanding variation and identifying trends or other patterns in the data over time
- Demonstrating the impact of interventions over time
- Displaying data in chronological order

A team needs just enough measurement to know whether the changes they are making are leading to improvement. To make measurement simpler and more effective the following points should be considered:

1. Plot data over time

Improvement requires change, and change happens over time. Much of the information about a system performance and how to improve it can be obtained by plotting data over time and observing trends and other patterns.

2. Use sampling to collect data

Sampling is a simple, efficient way to understand how a system is performing. Examples of sampling include collecting the data on every X-th patient to enter the primary health care facility or collecting data at set times during the day or on a set day of the week. Data can be summarized weekly using a median (the mid point from highest to lowest data values) or the average/arithmetic mean. Sampling is also a simple and efficient method of collecting data to identify change. The sampling technique focuses on getting ‘just enough data’ to demonstrate a pattern of change. More information is gained from a small sample size over a longer period of time than a large sample over a very short period of time. Fifteen to twenty plotted points are generally sufficient to recognize a pattern.

3. Provide information and training

Train those collecting data and integrate measurement into the daily routine. Ensure that all staff involved in the sampling process is aware of what the data are being used for. Develop simple forms for data collection if the data cannot be sourced from existing information systems, and make the data collection a routine part of someone’s job. Sampling will reduce the level of effort in data collection.

4. Create and display simple graphs

Create simple graphs to display information on the team’s progress toward its goal. The aim of the visual display is to present the maximum of information in the smallest space with the greatest impact.

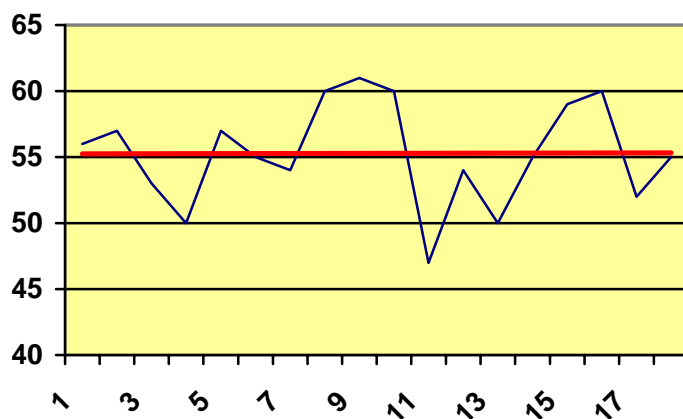
5. Refine the data collection process

Review your data collection process and consider how it could be improved.

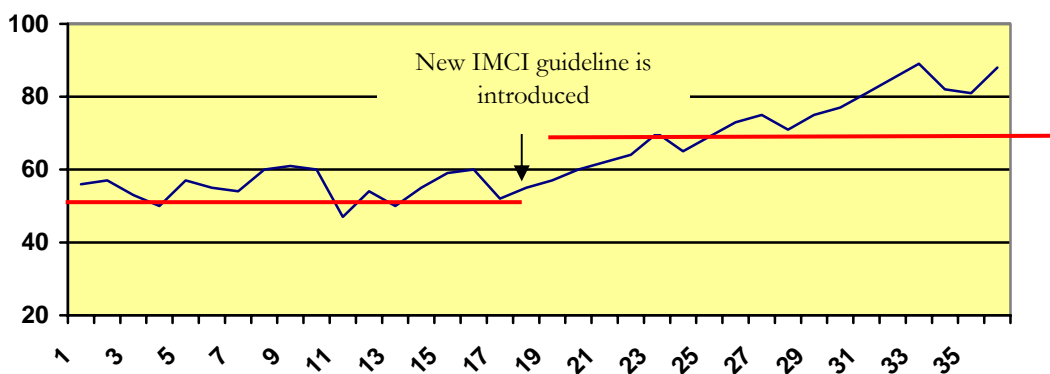
The key to Shewhart's concept is that there should not be an automatic reaction to each observation of random variation, but trends and patterns do require attention, hence decisions should be based on the nature of the variation. If variation is found there should be a thorough examination of possible causes.

The following example shows how run charts can be used to distinguish between common cause and social cause variation. The detailed interpretation of run charts is described in *Chapter VIII*.

In a region, 40 medical records of children under five in 10 primary health facilities were reviewed every month for adequacy of treatment and consultation for major child illnesses and preventive practices (pneumonia, diarrhea, anemia, vaccination and nutrition) during an 18 month period. Data was displayed on a run chart. The graph below shows the percentage of children that received an adequate (according to IMCI) treatment:



The researchers observed a random variation of data that is characterized by almost equal distribution of dots above and below the average line. It indicates that the performance of the system that produces compliance with IMCI remains the same, 55% on average. After that, primary healthcare workers (physicians and nurses) were trained in the IMCI approach and a new IMCI guideline was distributed, facilities continued to collect data on adequate (according to IMCI) treatment and consultation for another 18 months:



It was observed that starting with month 19, data are not randomly distributed around the average line but present a shift towards increase (more than 8 dots in a row are going in the same direction). A new average was drawn. The staff concluded that introduction of IMCI guideline led to a more adequate treatment prescription practice thus improving quality of care provided to children under 5.

In Short on Measuring Quality of Care

A measurement system is a key-feature of an improvement effort. The development of improvement measures is guided by three principles:

Indicators of quality should reflect the level of compliance with evidence-based standards of care, and the achievement of system performance outcomes;

A quality monitoring system responds to the immediate need to measure short-term results of improvement efforts and the long-term objective to institutionalize a dynamic of improvement through national indicators of quality;

A run chart is a convenient way to display improvement overtime and interpret variation in performance.

VII. The Management of Changes for Improvement

Why we need to make Changes

The central idea underlying modern quality improvement strategies is captured in the following phrase: "*Every system is perfectly designed to achieve exactly the results that it achieves*" (Donald Berwick²⁶). The level of performance (results) is a characteristic of any given system of work. A system left unchanged can only be expected to continue achieving the same results as before, even if individual data varies over time (normal variation in performance around the mean). To achieve a different level of performance, it is essential to change the system. For example, to increase the vaccination coverage from an average of 50% to 80%, specific changes into the vaccination system needs to be undertaken (outreach visits, special vaccination days, etc).

A challenge for each improvement team is to identify the main root causes of the problems and which changes would be the most effective and appropriate in addressing these problems. In this chapter we will discuss the factors that influence quality of care, elaborate on potentially effective changes, and talk about the logic of change implementation.

Investigating the Factors that influence Quality of Care

Having decided on the system to improve or the problem to solve, teams need to find out the causes of poor quality/performance. The focus should be on developing explanations why a particular problem or situation exists and why the system of interest produces the performance that is observed. This phase involves collecting and analyzing quantitative and qualitative data on the process being investigated to establish the causes of, and potential solutions to, the problem. Discussion of how the different causes interact to produce the problem helps the team to prioritize the causes and solutions to ensure effective action.

A problem, especially in a complex environment is rarely the consequence of one factor alone. There are three main players in the area of health that can be the causes of poor performance and the target for changes and interventions: providers that deliver healthcare, patients that receive healthcare and the system which is organized to allow providers to deliver and patients to receive healthcare (including policies and regulations, organization of health services, etc.). Subsequently, it is logical to conclude that all three can play a role in making the problem occur. Therefore, all 3 main targets should be included in the analysis:

- **Providers.** The team tries to determine the role of the providers in the occurrence of the problem. Potential causes include inadequate knowledge of providers, negligence especially in complex systems and highly stressed environment, etc.
- **Patients.** They can greatly influence the outcome of care by requesting a specific treatment, deciding whether or not to follow the recommendations, whether to buy all prescribed drugs or only a few, etc. Therefore, it is important to investigate what prevents patients to achieve desired outcomes.
- **System.** As mentioned above, both providers and patients operate in a system that influences behaviors. Any outcome is usually highly dependent on the system set up. For example, high number of patients per day leads to very limited contact time with the physician. As a result the physician can skip or forget to perform some clinical exams or investigation tests. If a patient is prescribed a drug that is not available at the closest pharmacy, then he is likely not to take the treatment and the outcome of care will be affected. These are examples where neither the providers nor the patients are the driving forces, but rather the system around them. As stated in a previous chapter, many things are included in

²⁶ Quality Improvement expert and Chief Executive Officer of the Boston-based Institute for Healthcare Improvement.

the system, but for pragmatic reasons we consider here that it is everything that is not the provider or the patient.

During this phase the team can use a number of diagnostic tools. These tools will help the team to study the system and its components, understand how it currently works, how the process affects customers/patients, and where opportunities for improvement exist. The tools might include the flowcharting of processes, brainstorming potential causes and solutions, developing a cause and effect diagram and collecting information to confirm hypotheses on causes. **Chapter VIII** provides a description of these tools, but we will focus here on the strategy for finding out the real causes, called root-cause analysis.

The main steps of root-cause analysis are:

1. **Identifying the potential causes of the problem** through brainstorming, by answering the main question “Why did the problem occur?” or “Why is that so?” and repeat the question 5 times (the “5 whys” technique) or until the final actionable answer is found. This technique is attributed to Taiichi Ohno, father of the Toyota Production System, which revolutionized automobile manufacturing. For example²⁷:
 - a. Why is a patient's intravenous run rate wrong? *The previous nurse didn't change the run rate.*
 - b. Why didn't the previous nurse change the rate? *The doctor's order had gone to the pharmacy and the medication administration record (MAR) was not updated.*
 - c. Why wasn't the MAR updated? *The MAR is updated only once per day.*
 - d. Why is the MAR updated only once per day? *The hospital has chosen to use oral instructions for updates that happen more frequently.*
 - e. Why are oral instructions used? *The process was constructed a decade ago, when medication orders changed less frequently due to longer lengths of stay. Upon further study, the hospital determines that 40 to 50 percent of its medications change every day.*
2. **Regrouping and displaying the causes.** All answers/causes can be organized under categories (using a technique such as affinity analysis) and displayed as a cause-effect (or fishbone) diagram (see **Chapter VIII** for an explanation of these tools). This allows making the links explicit between several causes.
3. **Confirm the reality of the causes** through the collection of data. The team needs to setup a data collection system or perform a quick survey to confirm the validity of the causes. Until causes are supported by evidence, they remain hypotheses.

It is important to involve the whole improvement team including leaders/managers and maybe patients in the root cause analysis discussion/brainstorming. The team should understand the processes they are investigating to ensure that appropriate and effective strategies are formulated and to ensure ownership of action by the team. After all it will be the team members who are going to be involved in testing the interventions to remove the causes, and the ones who are involved in the process are the most knowledgeable about it.

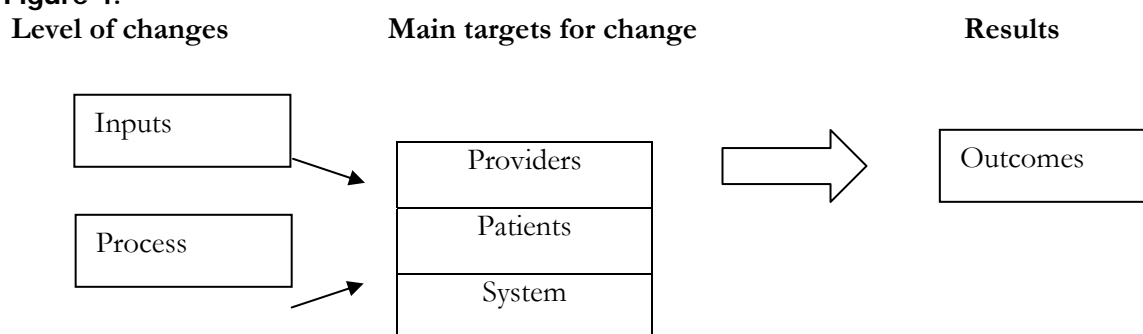
²⁷ Adapted from the Institute for Healthcare Improvement at www.qualityhealthcare.org.

Identifying Potentially Effective Changes

Once a team has identified main causes of undesired outcomes the next step is to think about potential solutions to the problems. There is not one “right” way to develop interventions that will produce improvement. The team should consider several points when identifying appropriate changes:

- A structured brainstorming session with all team members might help come up with ideas for interventions, system changes and solutions to issues, but might be limited by the lack of creativity of the team. Directed creativity tools can help²⁸, but they are uncommon and somewhat complicated to master.
- Changes should target the main categories discussed in the root-cause analysis: patients, providers and systems issues. For example, special interventions could target patients to better inform them about importance of iron supplementation and diet in treating anemia, this could improve their compliance with prescribed treatment – target at patient. Job reminders could be introduced for healthcare staff to remind them on some ‘problematic’ procedures – target at providers. Health facility schedule could be changed to better accommodate patient’s needs – target at system.
- The system’s view can help identify the types of changes and interventions. When outcomes are not satisfactory, changes need to target inputs and/or processes. **Figure 4** represents the interaction of the system view with targets of changes.

Figure 4.



- A typology of changes can prove very useful as a way to stimulate creative thinking about interventions that are more likely to lead to improvement. A classification of changes can have many subsets, but the following table provides a way to start categorizing those interventions according to the type of barriers to improvement that one wants to remove. **Table 9** presents another logic to identify changes.

Table 9: Identifying changes to remove barriers to clinical care improvement

Level of intervention Barriers to Improvement	The Individual (Provider or patient)	The System
Remove the causes that prevent providers from performing according to standards: performance improvement	Training Job Aids Motivation	Resources Time constraints Organization of services
Remove the causes that prevent patients to fully benefit from the performance of the providers: system improvement	Patient knowledge, understanding and empowerment	Lack of access to treatment Payment mechanism Regulations

²⁸ Creativity, Innovation and Quality. Paul Plsek. ASQ Publishing.

- Some experts developed a typology of changes summarized under the term “change concepts” presented below. **Table 10** presents a summary of change concepts, extracted from Langley, G.J. et al *The Improvement Guide: A Practical Approach to Enhancing Organizational Performance*.1996.

Table 10: Change concepts for the healthcare system

Change the work environment	<p>Give people access to information</p> <p>Take care of basics</p> <p>Reduce de-motivating aspects of pay system</p> <p>Implement cross-training</p> <p>Invest more resources in improvement</p> <p>Emphasize natural and logical consequences</p> <p>Develop alliance and cooperative relationships</p>	<p>Use proper measurements</p> <p>Conduct training</p> <p>Share risks</p> <p>Focus on core processes and purpose</p>
Enhance the producer/customer relationship	<p>Coach customers to use the product or service</p> <p>Focus on the outcome to a customer</p> <p>Reach agreement on expectations</p> <p>Optimize level of inspection</p>	<p>Listen to customers</p> <p>Use a coordinator</p> <p>Outsource for “free”</p> <p>Work with suppliers</p>
Manage time	<p>Reduce setup or startup time</p> <p>Optimize maintenance</p> <p>Reduce wait time</p>	<p>Set up timing to use discounts</p> <p>Extend specialist’s time</p>
Manage variation	<p>Standardize (create a formal process)</p> <p>Develop operational definitions</p> <p>Develop contingency plans</p> <p>Desensitize</p>	<p>Stop tampering</p> <p>Improve predictions</p> <p>Sort product into grades</p> <p>Exploit variation</p>
Design systems to avoid mistakes	<p>Use reminders</p> <p>Use constraints</p>	<p>Use differentiation</p> <p>Use affordances</p>
Focus on the product or service	<p>Mass customize</p> <p>Offer product or service anyplace</p> <p>Influence or take advantage of fashion trends</p> <p>Disguise defects or problems</p> <p>dimensions</p>	<p>Offer product or service anytime</p> <p>Emphasize intangibles</p> <p>Reduce the number of components</p> <p>Differentiate product using quality</p>

Implementing Changes

Having analyzed the system, mapped the process, identified the nature and causes of the problems associated with it, and determined potential solutions, the team then needs to find out whether these changes introduced in practice will indeed lead to an improvement or not. In other words, ideas need to be tested. Testing will tell us how to adapt/implement the change to suit local conditions, will help to evaluate costs and side effects of the change, and will minimize resistance to large-scale implementation. Testing on a small scale will ensure that efforts on a large scale are not wasted on changes that are not effective.

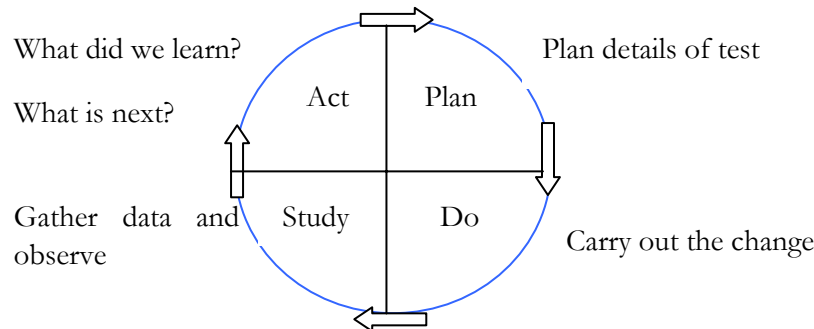
During the test, many issues can occur:

- Things may happen that were not planned, changing the environment within which the change is being tested;
- The change may have unwanted side effects;
- The change may not be implemented exactly the way it was planned.

The Plan-Do-Study-Act Cycle (or PDSA) is a useful tool to test changes. The method is based on a ‘trial and learning’ approach to improvement. The cycle consists of small-scale tests of planned interventions and changes (P & D), followed by assessment and improvement of the initial plan (S & A). If many changes are

planned, each one of them can be tested concurrently or consecutively with a PDSA cycle. The team learns from each test what worked, what did not work, why, and what changes/interventions should be kept, modified, or discarded. The team continues testing through PDSA cycles until an intervention is identified as suitable for broader implementation. **Figure 5** illustrates the dynamic of the PDSA cycle.

Fig. 5: PDSA cycle



1. The Phases of the Plan-Do-Study-Act Cycle

P=Plan to test selected change.

In this phase the team prepares a detailed plan including who will be involved in testing, what actions will be done, when the actions will start and how the changes will be evaluated.

D=Do the test (i.e. carry out the plan) and collect data for analysis.

As the change is being implemented, data collection may be as simple as counting observations and recording them on a tally sheet. It is essential to document problems and unexpected observations as these will help in understanding why a change did or did not result in improvement.

S=Study the results.

Compare data to predictions. Has the test resulted in an improvement? Can this be implemented on a larger scale? Analysis of the data will help identify reasons why the change did not produce the expected improvement and the exact magnitude of the impact of the change on the improvement objective.

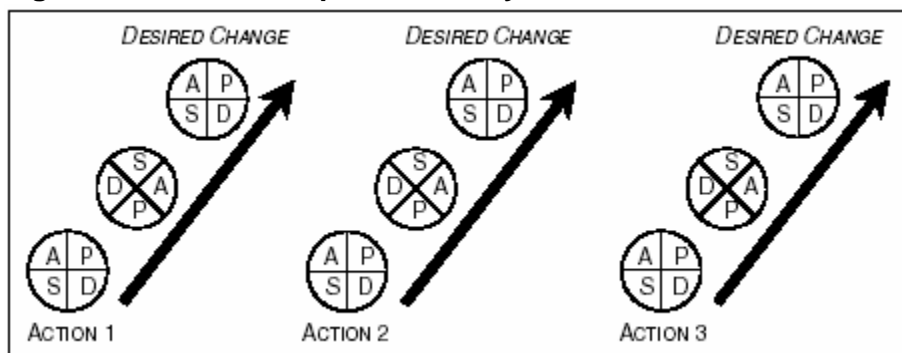
A=Act on the results.

Decide, based on results, whether to implement/replicate the changes or to select another possible change to test. Action should be rationally based on what was learnt from testing the planned intervention.

The main idea behind the PDSA cycle is to carryout a rapid test on a small scale (on one or two clinicians, or with the next 10 patients, or in one ward) to know in a very short time what changes might lead to improvements. After completion of a PDSA cycle, a team should know what worked and what did not work, what should be kept, changed, or thrown out. This new knowledge can be used to plan the next test and the new cycle. These linked PDSA cycles (sometimes called ‘ramps’) help overcome the natural resistance to change, because the incremental step-by-step approach is usually more readily accepted than a radical redesign of the entire system.

Teams may also be involved in testing more than one change at a time, ultimately aiming to achieve the same goal. Testing a number of changes at the same time is appropriate and teams should continue testing interventions or changes to achieve expected results. **Figure 6** illustrates the concurrent implementation of multiple tests and ramps.

Fig. 6: Concurrent ramps of PDSA cycles



2. Examples of PDSA Cycles

Example 1

Plan: A team participating in a quality improvement project pilot to improve the care for children decided to introduce a new IMCI form (2-page documentation for the medical chart) as a process change to facilitate IMCI guideline implementation. It was believed that the form would make it easier for the clinicians to follow the guideline recommendations.

Do: When the implementation team brought the new form to their facility, primary care physicians voiced concerns that the form would increase their workload within the already limited time available for each clinic visit. In response to these concerns the team asked two GPs in one facility to test the form on a small scale.

Study: After the test period, the providers using the new form reported that the form was easy to use and that it shortened the time it took to process children under 5. The reports were backed up with data.

Act: Based on these findings the action team implemented the document in all primary care facilities of the region, resulting in an increase of children being managed according to IMCI.

Example 2⁹

Plan: One facility decided to form a support and education group for families who had frequent emergency visits and hospitalizations for asthma in the previous 6 months. The first test was to have the asthma educator call 15 families and see if they would be interested in participating. When 13 of the families expressed interest, an initial support group was planned, including location, time and frequency of meetings, format, and content for both parents and children.

Do: Invitations to participate were extended to 32 "high risk" families. The initial meetings of the support group consistently had 18 to 20 families present. Brief asthma knowledge, symptoms and behavior surveys were administered at the beginning of each session.

²⁹ Adapted from Putting Practice Guidelines to Work in the Department of Defense Medical System: A Guide for Action, by W. Nicholas, D. Farley, M. Vaiana, and S. Cretin

Study: After three months, the educator observed that families with adolescent children had dropped out of the program, while those with young children had continued to participate, with evidence of improved knowledge and behaviors in the families who continued.

Act: Based on these findings, the original support program was redesigned to target families with children under 10. A review of those families from the original 32 invitees who never participated revealed that a large fraction of these families had teenage children. A decision was made to develop and test a different adolescent support group specifically aimed at preteens and teenagers.

Having policy-makers accept the idea that the system is here for refinement through testing can be a challenge, because it means dealing with uncertainty in our knowledge of what changes will be effective. Senior decision-makers usually prefer to make decisions on implementation of proven practices and are not comfortable with the concept that new ideas should be tested, because it involves taking a risk of failure.

In Short on Changes

Changes should be tested on a pilot scale before being implemented on a large scale, in order:

To build support among team members and to minimize resistance to the change upon implementation: Staff is more likely to accept the change if strategies are tested on a small scale. Members resistant to large-scale changes will be more receptive if they can provide input during a small trial run of the change strategy. Tailoring the strategy to the needs and concerns of the implementing staff will increase staff acceptance of change implementation.

To better predict the improvement resulting from a change and to determine the costs and side effects of the change: Testing changes on a small scale can be accomplished quickly with a minimal use of resources. At the same time, small-scale tests provide a good indication of problems and/or successes to expect from full-scale implementation.

To learn how to adapt a change to the conditions within the local environment: The experience and feedback gained from small-scale tests can be used to modify and improve the original implementation plan.

VIII. The Tools of Quality Improvement

In this chapter, we will describe the most commonly used tools in the management of a QI effort:

- Flowcharting a process
- Generating ideas through brainstorming
- Cause & Effect Diagram
- Affinity Diagram
- Run Charts

Flow Chart – To Understand a Process

Flow charts show the sequence of steps and decisions in a process. They help a team understand the process and how it can be improved. Flowcharts can identify activities that reduce effectiveness and efficiency. For example, some activities may be redundant or repeated, others may be unnecessary. Activities may be performed in sequence, when they could be conducted at the same time to reduce the overall time for the process. Flowcharts can be used to identify conditions that cause delays and bottlenecks. This can bring focus to problems at various points within the process that need further evaluation and improvement.

1. Benefits of flow charts:

- Shows how the process actually occurs
 - Encourages communication between both customers and suppliers
 - Illustrates the relationship of various steps in a process
 - Educates team members about all the steps within the process
 - Can be used to train new employees involved in the process
- Identifies who is involved in the process
 - Helps set boundaries of the process
 - Identifies team members needed
- Determines where the process can be improved
 - Useful for data collection
 - Immediate improvement opportunities may be identified

Boxes or other symbols represent different steps or actions. These step-by-step pictures can be used to plan a project, describe a process, and identify the steps that led to an adverse event or document a standard method for doing a job. They can help group members understand what is happening now in a process, as well as help them agree on the order of activities in a new, improved process. It is useful to flow chart a process at two levels:

- A high level flow chart (macro level) that describes the overall process. It illustrates how major groups of related activities interact in a process.
- A low level flow chart (mini level, or process flow chart) with more detail of the major stage in the process under examination.

2. How to develop flow charts:

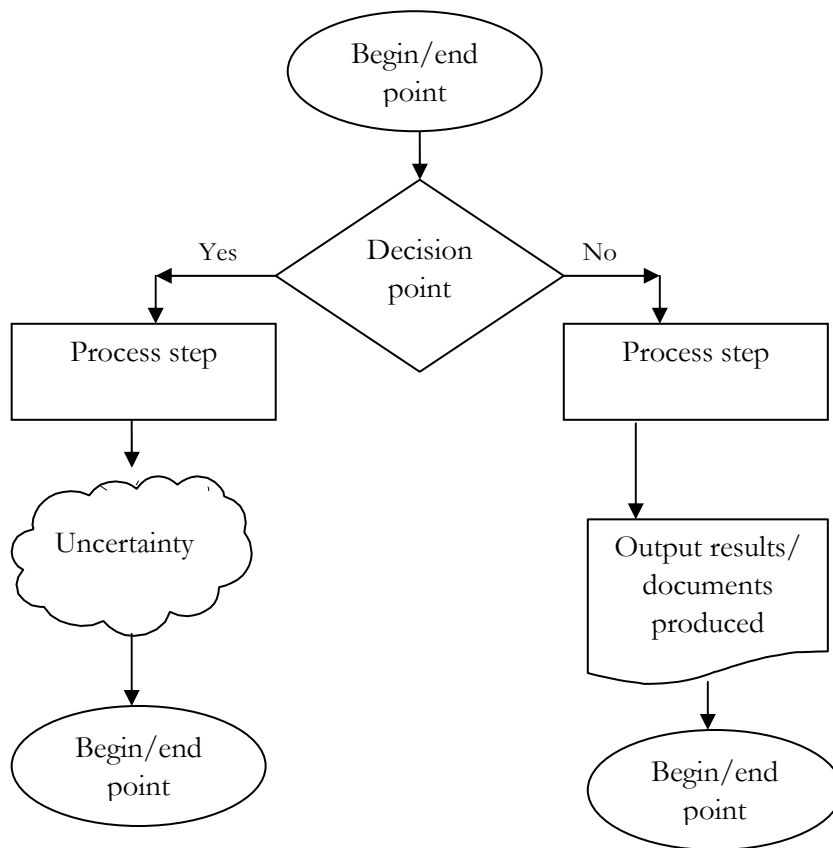
Step 1: Define the process to be studied. In particular, establish the boundaries of the process: where it starts, stops and interfaces with other processes

Step 2: Identify the steps within the process – as it currently happens, not how the team thinks it should be. Identify key activities or operations, as well as decision points.

Step 3: Draw the chart, using the appropriate symbols. Keep the flow chart simple and use arrows to show the direction of all steps in the process. Make sure the steps in the process are arranged in the order they are carried out. Having people with knowledge of the process involved in the activity should help ensure the flow chart is a true reflection of what actually happens.

Step 4: Finalize the chart after a process of reflection. Make sure it contains all key steps, including re-work and decision loops and the start and end points. Label the flow chart with the title of the process, the date, and members of the team involved in its preparation.

The basic symbols used when constructing a flow chart are:



3. Potential mistakes with flow charts

Failure to document the **actual** process is an important mistake that should be avoided. The failure to reflect reality may result from a variety of causes:

- Drawing the process as it was designed and not as it actually happens
- Team members are reluctant to draw parts of the process that might expose weaknesses in their areas.
- Rework loops are seen as small and unimportant and are overlooked
- Team members truly do not know how the process operates

4. Ways to avoid mistakes

- Be aware of the mistakes
- Have every team member commit to drawing the process as it truly is. (Build trust by focusing on process issues, not people issues.)
- Observe the process firsthand in areas where questions arise
- Obtain the assistance of staff in specific areas

The following steps will facilitate the construction of a flowchart.

List the steps involved in a process using direct observation, brainstorming, or consultation with the people responsible for each step.

2. Arrange the activities and decisions in chronological order, depicting each with the appropriate flowcharting symbol. Complete the big picture before filling in the details.
3. Show both the parallel activities and the sequence of events, all decisions that affect the flow of the process, all possible paths that things, work, and/or people take, even when unexpected events occur and / or rework must be done.
4. At each decision point, you have only two choices – yes or no. Choose one branch and continue flowcharting that section of the process. Complete flowcharting of the other branches from the decision symbols.
5. Circulate the flowchart to other people involved in the process to get their comments.
6. If different people or departments are responsible for different steps in the process, list the responsible parties across the top of the flowchart. Place each activity and decision in the process under the people or department responsible for it.
7. If possible, do a walk-through or observation of the actual process to verify the process as drawn.
8. Analyze the flowchart

Compare the actual process to what is desired.

Identify areas in which errors or problems could occur.

Identify time lags and non-value-adding steps.

Identify responsibility for each step.

Brainstorm for problems in the process.

Brainstorming – To Generate Ideas

The objective of brainstorming is to generate as many ideas as possible from team members. Such sessions are usually useful either when the team is trying to identify the causes of a particular problem or when the team is trying to identify the solutions to the causes.

There are two common methods for brainstorming:

1. Structured: Go around the group and have each person contribute one of their ideas in turn, until everyone is out of ideas.
2. Unstructured: Anyone calls out an idea, no order, until all ideas are exhausted.

Guidelines for brainstorming

1. Appoint a 'scribe' to write up the ideas.
2. Write the problem or idea or use a well-structured question on flipchart or board.
3. Start by reviewing the topic; make sure everyone understands the issues.
4. Give people a minute or two of silent thinking time.
5. Write all ideas on 'Post-It' notes and place them on flipcharts or a board so everyone can see them.
6. Agree to no discussion during the brainstorm. That will come later.
7. Agree to no criticism of ideas – not even a groan or grimace!
8. Build on ideas generated by others in the group.
9. Leave historical solutions behind; think fresh, be creative.
10. Focus on creating a new order rather than discussing the old problems; do not use words like: less, more, better, not, as they tie you to current problems.
11. Use complete sentences (5-7 words) with noun, verb, and object – to help clarity.

The next step is to identify the priority issues for the group. Some form of voting or affinity analysis usually achieves this. In a small group discussion a show of hands may be sufficient. When the issue is more complex and more people are involved, consensus may be unlikely in the time allowed. In this instance, multi-voting may be the best option.

Cause & Effect Diagrams - Identifying the Likely Causes of Problems

Also called Fishbone Diagrams and Ishikawa Diagrams

Cause and effect diagram is an effective tool for organizing and categorizing ideas generated in a brainstorming session. It helps you to think through causes of a problem thoroughly. The diagram's major benefit is that it pushes you to consider all possible causes of the problem, rather than just the ones that are most obvious.

How to use tool:

Step 1: Identify the problem

Write down the exact problem you face in detail. Where appropriate identify who is involved, what the problem is, and when and where it occurs. Write the problem in a box on the left hand side of a large sheet of paper. Draw a line across the paper horizontally from the box. This gives you space to develop ideas.

Step 2: Work out the major factors involved

Next identify the factors that may contribute to the problem. Draw lines off the spine for each factor, and label it. These may be people, systems, equipment, materials, external forces, etc. Try to draw out as many factors as possible.

Step 3: Identify possible cause

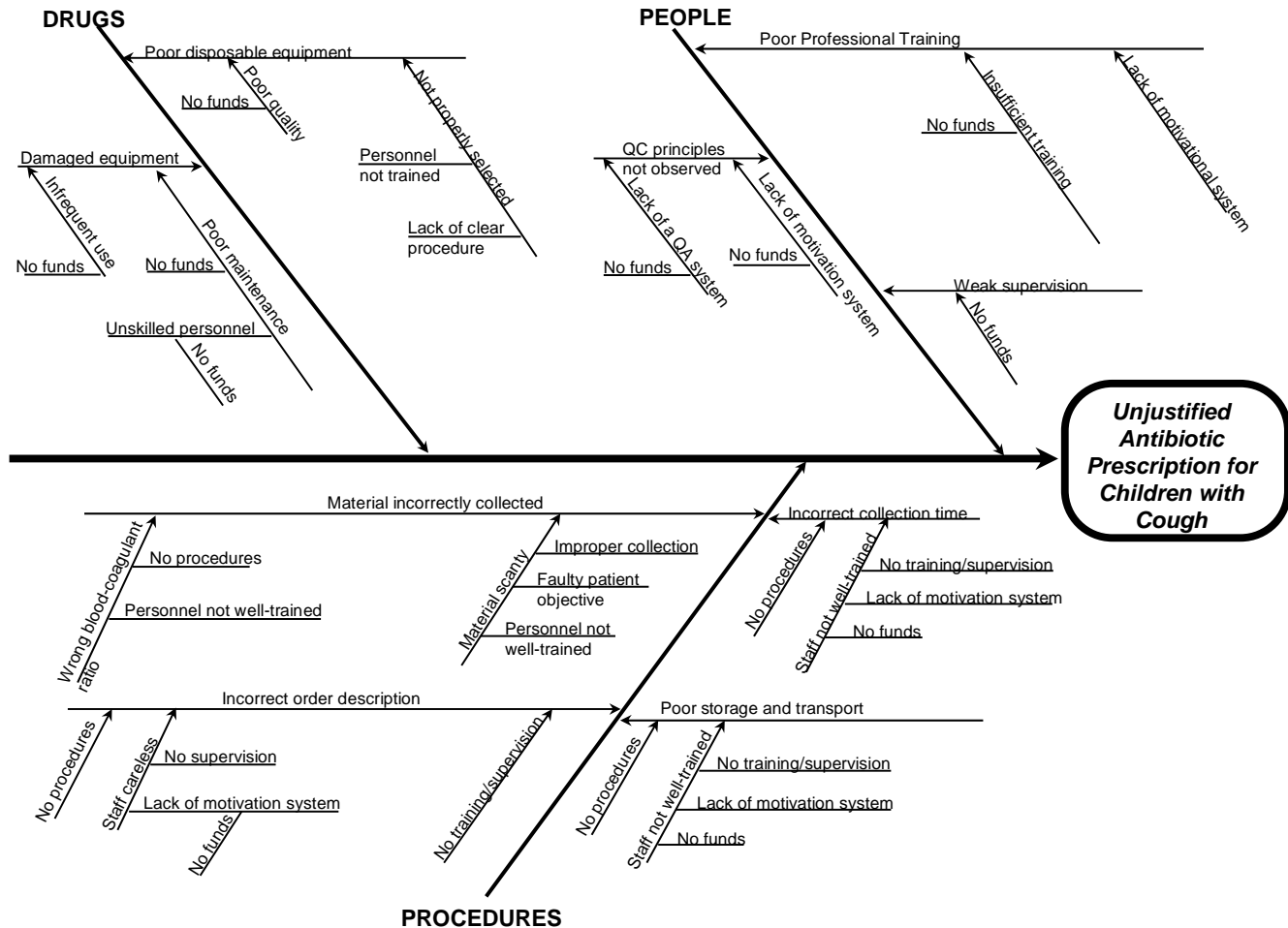
For each of the factors you considered in step 2, brainstorm possible causes of the problem that may be related to the factor. Show these as smaller lines coming off the 'bones' of the fish. Where a cause is large or complex, then it may be best to break it down into sub-causes. Show these as lines coming off each cause line.

Step 4: Analyze your diagram

By this step you should have a diagram showing all the possible causes of your problem. Depending on the complexity and importance of the problem, you can now investigate the most likely causes further. This may involve setting up investigations, carrying out surveys, etc. These will be designed to test whether your assessments are correct.

Example of Cause and Effect diagram

CAUSE-EFFECT DIAGRAM



Affinity Diagram –To Organize Ideas and Thinking

An Affinity Diagram is another useful tool for gathering and organizing ideas, opinions, or issues identified by a team. Ideas generated through activities such as brainstorming are usually naturally related. The Affinity Diagram identifies the theme for each group of ideas and gives each group a header or title.

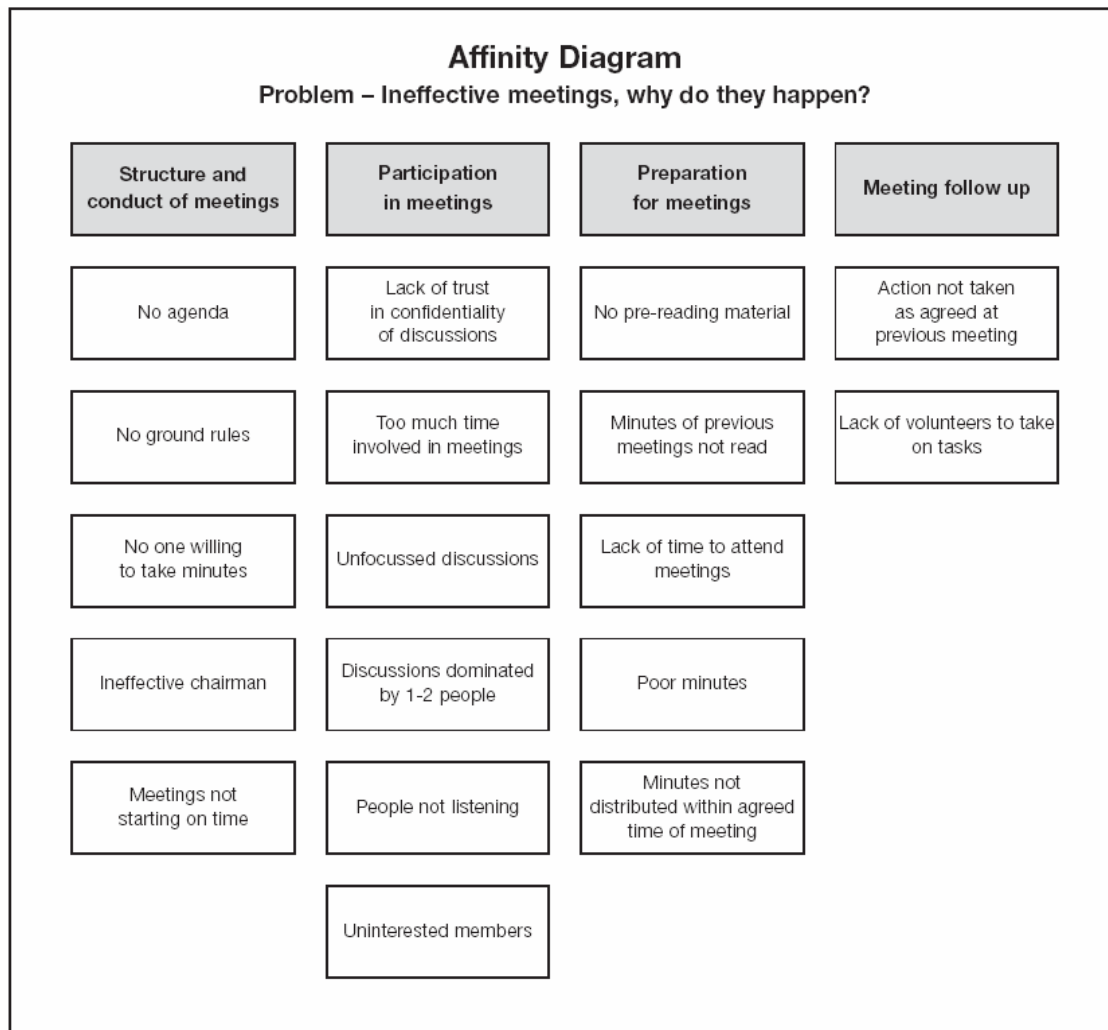
An Affinity Diagram may be used when a team is seeking to:

- Add structure to a large or complicated issue (eg. useful when identifying the central issues involved in developing a new service).
- Break down a complicated issue into broad categories (eg. useful when identifying the major steps in the completion of a complex project).
- Gain agreement on an issue or situation (eg. Useful when needing to identify the direction to be taken to achieve a particular goal and for minimizing the potential for conflict).

Steps in constructing an Affinity Diagram

1. Start with a clear statement of the problem or goal to be explored. Provide a time limit for the session: 45-60 minutes is usually sufficient.
2. Brainstorm ideas related to the issue or problem. Ask each participant to write their ideas clearly on index cards or 'Post-It' notes, one idea per card (five to seven words per card in large print is suggested).
3. With the assistance of a facilitator, group the cards or 'Post-It' notes in columns according to ideas that appear to have a common theme. Do not allow discussion of issues at this point.
4. Review the lists to ensure all ideas are appropriately grouped under a common theme. Regroup if necessary. Do not search for relationships between issues. It is sometimes best to leave a single issue (single card) on its own rather than add it to a group and blur the issue.
5. Give each grouping a title or heading that best describes the theme for each group of ideas. This should express why the group believes the particular set of ideas 'go together' and is usually written as a short action statement (verb).
6. Having reduced the number of ideas to manageable groupings, discuss and prioritize the issues according to their relative importance and potential impact on current performance.

Example of an Affinity Diagram



Graphs and Charts – To Display and Analyze Data

There are many commonly used techniques for helping visualize changes in a process over time or comparing performance before and after an intervention. They include:

- The bar graph which presents data collected in a way that helps visual relationships between different **categories** of factors.
- The pie chart which shows parts of a whole. Results are usually presented as percentages. As the title suggests, this form of graphical tool clearly illustrates how ‘the cake is divided’.
- The histogram which uses bar charts arranged in a numerical continuum, illustrates patterns of variation in a process and is particularly useful for depicting variation in a particular process over time.

This section features the run chart because it has been found particularly useful tools to use in the field of quality improvement.

Run Charts – to display data over time

A run chart (sometimes called a time plot or line graph) can assist in understanding variation and is used to examine data for trends or other patterns that occur over time. It graphically depicts the history and pattern of variation in an indicator or measure. Plotting data regularly on a run chart shows when shifts and changes occur and can help identify if and when problems appear. The run chart is one of a number of tools that help people see patterns or trends in data over time.

Benefits of run charts:

- Helps in understanding variation and identifying trends or other patterns in the data over time;
- Demonstrates the impact of interventions over time
- Useful for displaying and plotting data in chronological order.

Teams should begin collecting data before they intervene and then graph the results of the intervention to measure change in the process. It is best to note on the run chart when specific interventions occurred so that any resulting changes to the process are more readily seen. By annotating the run chart in this way, it is easier to understand the impact of changes made over time. It is also important when interpreting a run chart, not to see every variation in the data as significant. Over time, the run chart is useful for identifying the impact of interventions, for demonstrating long-lasting improvement, and for identifying shifts and trends in performance that may indicate the need for further intervention.

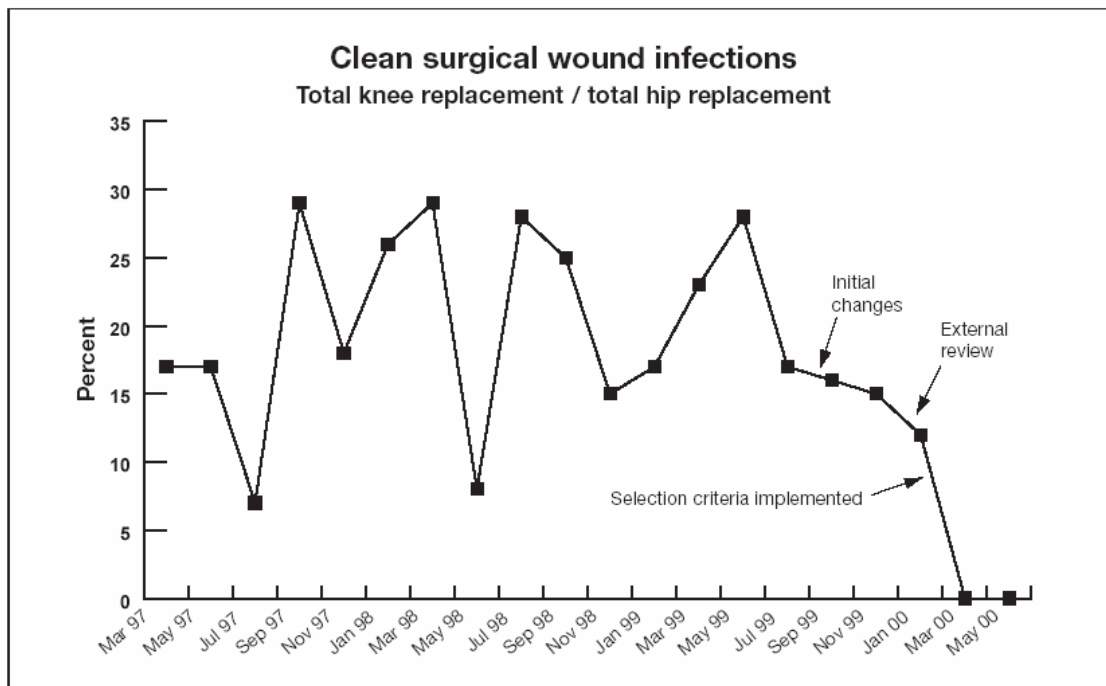
Interpreting run charts

If you have at least 25 or more data points in the analysis, you can use a run chart to detect special causes, which is something beyond the usual variability of the process that acts on the process. To do the analysis, you first need to determine the mean – the average – of the data points you want to analyze. This may mean calculating two means – one before an intervention, and one after.

- **Shifts:** If seven or more consecutive points fall on one side of the mean, without crossing the mean, it suggests that something special has influenced the process.
- **Trends:** Seven consecutive points in the same direction indicate that a special cause may be acting on the process to cause a trend. Flat line segments are not included.

- **Pattern:** If you see a pattern of up and down points (“sawtooth”) that recurs seven or more times in a row (comprising 14 data points), it likely indicates a special cause.

Example of a Run Chart



The advantage of using run charts is that they do not require statistical analysis.

IX. The Large-Scale Replication of Improvements

Introduction

The pilot phase of any improvement effort is to learn about what changes (most of them at system level) are effective to improve quality on a small scale. However, if we want improvements to impact the health outcomes of a population, then the changes that produced these improvements must be replicated on a large scale, which means that they need to cover a much larger number of units, whether health facilities or providers or any other target for replication.

The large-scale replication of changes is an undertaking that has its own set of specific challenges and is usually implemented through a dynamic very different than the one in the pilot phase. In the replication phase, the objective is to reach as efficiently as possible the targets for changes, whether health facilities, a group of patients, the entire population, or any other component of the system of care. The replication plan is developed to cover quickly a large number of units with interventions known to be effective and avoid reinventing the wheel (rediscover through testing which changes lead to improvements).

However, the adoption of changes by new units is not a mechanical activity and part of the replication strategy consists also in equipping the new adopters with the skills to adapt the change through the use of QI cycle and tools, not just replicate changes as they are.

In this chapter, we will look at the theories of replication, the content of the replication strategy and the replication process.

The Theories of Replication

The main theory behind a replication strategy is the “diffusion of innovations” theory. The spontaneous adoption of new practices throughout a social milieu was studied to draw some conclusions that can be used to plan the introduction of the next practices that should be adopted because they are proven to be beneficial to the society. From research, generalizations were made to help design replication strategies and plans.

In the reference book on the diffusion of innovation³⁰, Everett Rogers defines “diffusion as the process by which an innovation is communicated through certain channels over time among the members of a social system”. This definition highlights the 4 elements to take into account when designing a replication strategy:

- The innovation. This is the new clinical care or management practice that has to be adopted by new users. For example: a new clinical practice guideline, a new way of organizing healthcare services, a new health financing system, etc. We must have evidence that the innovation that we would like to replicate is leading to improvement, and this evidence comes from what we learned during the pilot phase.
- The communication channels. They represent the ways by which the information about a new practice (a change) is communicated to individuals who have not adopted it yet. The change is more likely to be adopted if the people who discovered and implemented it during the pilot phase are actively involved to communicate it to the new adopters. This peer-to-peer relationship is more likely to work than if the change is communicated through people who have not been involved in the pilot phase or have only a hierarchical and authoritative relationship with the new adopters.

³⁰ Rogers, Everett M. Diffusion of Innovations. 5th Edition. Free Press.

- The time. The pace at which a new practice is adopted by new units (for example providers practicing according to a new guideline) follows a similar pattern across systems: some people adopt it early, then the vast majority will adopt it later, and some people won't adopt it at all. This allowed identifying 5 categories of adopters: innovators, early adopters, early majority, late majority and laggards. The speed of adoption varies with the innovation but the distribution of adopters remains the same. If it is possible to identify these categories of adopters early in the replication phase, then the replication strategy can be designed to allow for some customization of the communication channels to each category, since the various groups of adopters respond differently to the way the innovation is communicated. For an innovation to spread more effectively, early adopters are more useful agents of change, because innovators are often not representative of the system.
- The social system. This is the milieu within which the diffusion is expected to occur. The system is defined through the accomplishment of a common goal and it has its own boundaries. General practitioners working at primary health care units are an example of a social system. Knowledge of the social system is useful and requires understanding of the structure (who has authority to push for the adoption of innovations?), the existing norms (what are the patterns of acceptable behaviors?), change agents and opinion leaders (who influences who?), the way innovation decisions are made (degree of autonomy by the individual) and the consequences of the innovation (for both individual adopters and the whole system).

Because the adoption of innovations requires that many individuals change a practice (for example a medical practice), the theories of individual behavior change are important to know. A useful model is the 5-step model of Prochaska, DiClemente & Norcross. This model states that an individual goes through 5 stages for adopting a change: pre-contemplation, contemplation, preparation, action and maintenance.

- In the pre-contemplation stage, the individual is aware of a problem and starts thinking about how to solve it. For example, a health provider might notice that a certain treatment is not effective.
- In the contemplation stage, the individual thinks more seriously about a solution but has not decided to implement it. For instance, the physician gets information about more effective treatments.
- In the preparation stage, the individual intends to take action. For example, the physician decides to try a new treatment.
- In the action stage, the individual tries the new practice. For example, the physician prescribes the new treatment instead of the old one.
- In the maintenance phase, the individual sustains the new behavior because of the perceived benefits. For instance, the physician abandons the old treatment and continues to prescribe the new one.

This knowledge of behavior change theory is useful because it teaches us that individuals want to see for themselves that a change is an improvement and might not be convinced by just learning about the experience of others. Even when research brings information on the benefits of a new medical practice, individual physicians need to be convinced through their personal experience with patients. This information justifies designing and replicating the improvement monitoring system that was setup during the pilot phase in the new units for replication.

What do we Want to Replicate?

Two types of innovations coming from the pilot phase of the improvement effort must be replicated: the changes that lead to improvements and the improvement process itself. There are two reasons to not limit the replication to the change only:

1. The context within which the change is replicated might be different from the context in which it was discovered in the pilot phase. Because of this difference, the adoption of the change might require some adaptation. For example, in the Ferghana oblast of Uzbekistan, it was found that the Sali hemometers used for the diagnosis of anemia gave wrong results. The improvement team decided to calibrate the machines through a process involving the reference laboratory. However, for some districts/rayons, the reference laboratory is too far and the calibration process cannot be performed on a regular basis. These teams decided to buy new machines, instead. In this situation, successful replication of improvements does not mean the adoption of a unique solution tested elsewhere, but the use of QI tools for generating and testing new ideas to achieve the same goal.
2. Sustaining the quality improvement dynamic is an objective in itself and requires expansion to all units. The units for the replication of improvements must be equipped with the knowledge and skills to carry out their own pilot improvement projects on a continuous basis. This will allow them to discover new effective practices and changes on the same topic or to start improvement projects on a different topic.

In the Ferghana experiment, the following activities were replicated:

- The standards of clinical performance that were developed in the pilot phase were distributed to all medical units;
- The quality monitoring system, indicators and forms developed during the pilot, were implemented;
- The teams were trained in the quality improvement cycle.

Because the new units do not have to start from scratch, the replication strategy is much more efficient and faster, with a level of effort per unit significantly decreased. For example, in Ferghana Oblast, it took almost 2 years to identify effective changes that lead to improved quality of care in 3 pilot rayons, i.e to learn about how the system “behaves”. Once better practices were discovered, the oblast decided to spread them over the remaining 13 rayons of the Ferghana Oblast, to reach all 273 primary care facilities. The replication strategy is implemented 3 rayons at a time, covering them with the interventions described above over a period of 3 months only. This is about 8 times faster than the original pilot phase.

How do we Spread Improvements?

There are several types of replication strategies, depending on the amount of decision-making authority that individuals have to change a practice.

In a decentralized system, where improvements come from the initiatives of entrepreneurs, it is often enough to inform them of the existence of a better practice, or of a problem that they need to address. In this situation, the innovation is spontaneously adopted and the role of the change agent might be limited to disseminating the information through appropriate communication channels. This is referred to as a pull strategy.

In centralized command and control systems, it is unlikely that peripheral units will take the risk to implement a change not supported or required by the higher levels of authority. In this situation, the central level issues an order to implement a new practice, a plan is developed and peripheral units have no choice in its implementation. This is called a push strategy.

These situations represent the two ends of the spectrum on a continuum of decision-making and management styles. All alternatives in between exist, and we recommend considering a mix of a pull-and-push approaches in order to ensure the chances of success.

Key lessons learned from experiences can help design the replication strategy. **Table 11** lists the guiding principles of a replication strategy and illustrates how they were applied to the Ferghana improvement projects.

Like for the field of QI in general, it is important not to adopt a narrow view of the replication phase as a universal recipe, with its set of rigid steps. Although there is no alternative to a step-by-step implementation of any plan, it is more important to use the replication principles to design a strategy that makes sense in a specific context rather than importing a plan that was successful in another context. This is why the Ferghana replication plan is provided here only as an example.

It is also important to mention that in Ferghana, the decision was made to replicate best practices on a continuous basis, and not to wait for the perfect system to come out of the pilot phase. So, while the pilot rayons keep looking for effective changes, the new rayons implement the ones already discovered.

In Short on Replication of Improvements

A replication strategy is guided by the following principles from the diffusion of innovation theory and behavior change models:

The change must be proven to be beneficial through the pilot phase;

The communication of the change must involve the people who discovered and implemented it during the pilot phase to support the new adopters;

The effectiveness of various communication channels depend on the category of adopters;

The structure, norms and decision-making of the social system must be known;

The behavior change process at individual level justifies replicating the improvement monitoring system from the pilot phase;

The replication strategy is a mix of spontaneous adoption after dissemination of information, and thorough planning involving decision makers at the top and implementers at the bottom;

The spread of the replication must be measured and lessons learned about factors of successes and challenges in order to plan the next phase more effectively.

Table 11: Features of a Replication Plan to Spread Improvement; Theory and Application to Ferghana.

Phase of the Replication Plan	Replication Principles	Ferghana Replication Strategy
Plan (PLAN)	Get support from the higher levels of the health system and the leadership	The Ferghana Oblast health management team decided to expand the pilot improvement projects from 3 to 16 rayons, taking initiative and ownership.
	Develop a replication plan that involves all parties	During a 2-day conference, new rayons developed a plan for replication, with support from the pilot rayons and the oblast management team.
	Select opinion leaders and early adopters in the new units for spread	The new rayons targeted for spreading improvements were selected based on their openness to change, local condition for implementation (for example, access to computers), and on their volunteering.
	Assign responsibilities to teams	In each SVP, a replication team has been set up, which is the target of the training sessions and is responsible for the implementation of the improvements.
	Make explicit the new practices to spread in terms of clinical processes and organization of healthcare services	Pilot rayons developed change packages that list all interventions they made to improve clinical performance and quality of care. These packages are used as objectives for replication in new rayons.
Implement (DO)	Give a key-role to the implementers of the pilot phase to support the spread of the improvements;	Chief oblast specialists and pilot rayon coordinators were trained as trainers in QI and facilitators of the spread to new rayons. They perform a mentoring role through field visits
	Build the capacity of the new adopters (rayons) in clinical performance	A 2-day training exposed the staff of the new rayons to the new evidence-based guidelines, the standards of performance and the indicators used in the pilot phase.
	Involve experts in the clinical care content for improvement	Both the developers of the evidence-based CPGs and the oblast chief specialists delivered the training mentioned above.
	Replicate the monitoring system to tell new adopters about the impact of the innovation in their context.	The quality monitoring support is being extended to all new health facilities targeted by the replication, through the support of rayon coordinators of the pilot rayons
	Build the capacity of the new adopters (rayons) in the QI process	A 2-day training (delivered by republican QI trainers) exposed the staff of the new rayons to the QI cycle.

Assess and Evaluate (STUDY)	Develop mechanisms for new adopters to share experience and learn from each other	Weekly meetings between rayon coordinators and heads of SVPs are used to discuss the QI spread activities. A quarterly newsletter, the “Journey to Quality”, reports on the replication strategy.
	Maintain support from the leadership in the replication process and the changes for improvement	The Oblast quality management team is informed regularly of the progress and issues with the replication plan.
	Measure the extent and pace of the spread, so that one can follow the coverage of the adoption units by the innovation over time.	Four republican-level trainers (from 2 training institutions) perform quarterly visits to the new rayons to assess the level of spread, using a measurement tool.
Refine the replication plan (ACT)	Draw lessons from the replication phase itself in order to move to the next stage of the replication, as it is unlikely that the replication will cover all geographic units at the same time and will go unchanged.	Four republican-level trainers perform quarterly evaluation visits to report on factors of successes and issues with the replication strategy. Lessons learned will be used to adapt the replication strategy to the other rayons.

X. The Institutionalization of Quality Improvement Activities

The concept of institutionalization embodies several ideas:

- **Sustainability** of functions and activities (improvement processes keep being performed);
- Complete geographic **coverage** (best practices and interventions are adopted system-wide);
- Specific **structure** (human resources are given an explicit mandate to focus on quality of care issues);
- **Integration** of activities (quality improvement activities are performed on a regular basis, as part of the work);
- **Coordination** of activities (through clarification of roles and responsibilities of all stakeholders).

The overall idea is to establish an improvement dynamic that will stay and evolve over time because quality management is the way the healthcare system should operate and not just a time-limited vertical program. It is a way of working, not a project.

Institutionalization usually requires making changes at a high level in the system. This is always more difficult than the management of a small-scale pilot QI project and has its own set of challenges. Little is known about this complex aspect of a QI effort and the factors that influence the institutionalization of QI mechanisms. The main reason is that there have been very few formal attempts by national healthcare systems to institutionalize management processes and design the healthcare system around the central objective of improving quality of healthcare services.

What do we Want to Institutionalize?

Based on international experiences, we know that a certain number of activities contribute to improving the quality of care and performance of the health care system. Not all experiences have been studied with the rigor required for randomized clinical trials, but the nature of the topic is a challenge for traditional research methods. As a result, the strength of the evidence available is sometimes limited to the opinions of QI experts, and sometimes supported by success or failure stories. It is helpful to think in terms of functions to be fulfilled by the national health system, derived from its mandate to improve the health status of the population. The following functions should be considered by the health authorities for improving the performance of the healthcare system with a focus on quality of care:

- Leadership for Quality:** as the steward of the health system, the Ministry of Health should be the overall leader of the QI strategy. In practice, leadership at every level and within each stakeholder needs to be present for success. The existence of “champions” motivated to make things work is a key characteristic of successful quality activities, and institutional leadership (legitimized by an official position) is more effective when it comes with charisma and technical credibility, and is relayed at all levels of the healthcare system.
- Facilitation & Advisory Functions:** a “structure” should be in charge of facilitating and advising the MoH and its partners on the issues and progress regarding the implementation of the QI policy/strategy. By doing so, this structure will promote coordination of activities and stakeholders.
- Advocacy Function:** sensitize and convince various audiences of the importance, features and impact of the QI strategy. This is basically a shared responsibility between the MoH and the coordinating structure. The advocacy role also consists in identifying incentives and disincentives for quality activities and promote the motivation of all involved to raise their standards of performance.

- d. **Execution/Implementation Function:** this is where roles and responsibilities of all stakeholders must be clearly identified to carry out the following (and non-exhaustive) list of activities:
- Promotion of evidence-based medicine, including the development and revision of evidence-based materials (guidelines and protocols, etc.) and their dissemination/implementation;
 - Quality monitoring systems at facility and regional levels, and measurement of national indicators of quality/performance;
 - Specific facility-based quality improvement projects;
 - Development of patients' charter describing rights and obligations and recourse mechanisms in case of dissatisfaction/complaints;
 - Health technology assessment;
 - Licensing and certification of health professionals;
 - Accreditation of health facilities;
 - Safety programs and projects.
- e. **Teaching Function:** training mechanisms, whether undergraduates, post-graduate or through continuous medical education, represent opportunities to build the knowledge and skills needed to carry out the various quality activities listed above. Health professionals, both clinicians and managers, must be competent in evidence-based medicine, knowledge management, performance assessment, team work, quality improvement and interpersonal communication, just to name a few capacities that are not traditionally taught in medical schools. It might be relevant to consider some advanced training in QI for building a network of resource-persons at the regional/county level. The equipping of libraries with specialized quality literature, whether electronic or hard copies should be part of this component.
- f. **Monitoring & Evaluation:** the coordinating structure must develop a monitoring and evaluation plan with focus on the implementation processes and results of the QI strategy. The plan should describe successes and failures, analyze their causes, promote reflection among stakeholders and make recommendations.
- g. **Research:** research departments and universities have an important role to play to assess the effectiveness of the QI policy and its individual components on quality of care. However, field implementers, not researchers, must identify specific operations research topics so that results respond better to their needs and inform the adaptation/revision of the policy/strategy.
- h. **Communication:** Both the content and the channels of communication must be identified between all stakeholders of the QI strategy. A stakeholders' matrix could be developed to identify the communication links to be created (who communicates what to whom). It is very important, as issues are as much in the connections between components of a system as in the way individual components perform. For example, the structure in charge of providing medical equipment to facilities needs to work with the structure in charge of developing guidelines, since evidence-based recommendations might require equipment that is not available.

When these functions are carried out in an integrated way and on a continuous basis, one can consider that quality improvement is institutionalized into the health system. Some projects have defined stages of institutionalization, but they are more pedagogical than scientific. Nevertheless, they can be useful in identifying what next steps are needed.

What is the Institutionalization Process?

Institutionalization of the functions listed above is unlikely to happen without a structured and concerted effort that aims at developing a QI policy or strategy. Although there is no recipe, some features of the policy development process deserve consideration:

1. Do we need a conceptual framework?

Because both quality management and institutionalization are abstract concepts not familiar to most ministries of health, the development of a conceptual framework can help designing a QI policy/strategy. Each country must develop its own framework, and we cannot recommend one framework as a benchmark, but we will describe the one developed by the MoH in Kyrgyzstan as an example. In Kyrgyzstan, the MoH decided to build a framework based on the following features:

- The framework makes explicit a clinical definition of quality, which is the result of an interaction between a patient and a health provider (or population and system) and has 3 dimensions (3 measurable criteria): effectiveness (the care leads to better health); efficiency (patients do not receive more care than they need); and safety (the care does not hurt the patient).
- Six factors were identified as the ones influencing most and more directly the quality of care, as defined above: providers' competency; providers' motivation; providers' access to resources and information; patients' access to resources and information about health system and their rights; specific quality improvement activities, such as the promotion of EBM, the measurement of quality of care, and QI projects; and healthcare regulations.
- The components of the healthcare system involved in the production of these factors were identified. For example, the framework helped identify the training institutions and mechanisms that contribute to the production of a competent provider. Systems (or sub-systems) were thus identified and, with them, all stakeholders who take part in the healthcare system and therefore have a role to play in QI.
- For each factor, a long-term vision of a better system was developed, describing, for example, what a more competent and motivated provider would look like and do to deliver better care.
- For each factor and its related sub-systems, a list of improvement objectives and interventions were defined to achieve the vision. For example, it was found that undergraduate medical students lacked knowledge of the evidence-based medicine approach and lacked skills to update their clinical knowledge. It was recommended to develop a course in EBM and knowledge management at the medical academies.

The Kyrgyzstan conceptual framework for quality improvement is reproduced on the next page.

Conceptual Framework for the Institutionalization of an Integrated Quality Improvement System in Kyrgyzstan

Definition of Quality

Factors influencing quality

Underlying Concepts

Competent Provider: Knowledge and skills to implement evidence-based practices, update knowledge, measure performance and improve quality

Improve both content and process of clinical education;
Consider all educational opportunities (undergraduate, postgraduate, continuous medical education) to familiarize providers with evidence based-guidelines and protocols and build skills in Evidence-Based Medicine and Quality Improvement; and
Equip providers with knowledge management skills.

Motivated Provider: Willingness to implement guidelines, real concern for patient care, involvement in improvement activities, professional attitude

Understand incentives and disincentives to do better in the current system and expand motivation mechanisms beyond just financial rewards;
Modernize human resources management; and
Rely on self-regulations from professional associations.

Providers' Access to Resources and Information that are necessary to deliver care according to evidence-based guidelines and protocols and contribute to improving the overall performance of the health care system

Ensure consistency between the allocation of resources and guidelines/protocols;
Make necessary information accessible to all providers so that they have a comprehensive knowledge of the health care system and are up-to-date with changes; and
Make sure health financing mechanisms contribute to the above goals.

Quality of Care:

Effectiveness, Efficiency, and Safety

Patient's Access to Resources and Information, Demands and Rights: Raise demand for quality, express dissatisfaction, address issues, exercise rights and obligations, participate in improvement activities

Inform patients of their rights and obligations, including their health insurance coverage;
Promote involvement of patients in improving quality of care through more rational demands, mechanisms to address dissatisfaction, and involvement in quality improvement projects;
Strengthen dialogue between providers and patients and population, including patients' associations;
Inform and educate the population on healthier lifestyles; and
Increase access to drugs that have an added value and decrease access to unnecessary drugs.

Specific Quality Improvement Activities: Development of evidence-based standards, quality monitoring, and continuous quality improvement efforts

Promote the delivery of evidence-based medicine;
Monitor and evaluate the quality of care, including through the health information system; and
Implement specific clinical care quality improvement projects.

Regulations: licensing, certification of specialists, accreditation, and health legislation

Make sure current licensing, certification and accreditation systems are consistent with evidence-based standards, and are effective in improving the quality of care; and
Review any other regulation that influences the interventions related to all other factors.

2. What is the process to develop a QI policy?

Because the policy development process is very specific of the history of each country, we cannot recommend a specific and unique process. However, the following features should be considered for a successful policy development process:

- Because many stakeholders will be involved in improving quality of care, it is important that they all participate in the development of the QI policy. Therefore, a “democratic” process of involving people and institutions must lead the policy development. It should not be a top-down approach where people discover or guess what to do through a regulation.
- The development process requires organizing many meetings and discussions on specific topics with various groups. The composition of the groups must be relevant to the topic, but it is important to discuss the issues in depth rather than rush to obtain a consensus. Policy development provides an opportunity for all involved to discuss issues that they might never discuss otherwise. It creates a forum for in-depth reflection of a group of people who do not usually meet.
- A national consensus conference might be useful to present the work of the groups and get final approval from all participants. In Kyrgyzstan, a national conference allowed all partners to approve the framework and plan the next steps.
- A structure is needed to manage the policy development process, with clear terms of reference. In Uzbekistan, a three-level structure was recommended: i) a steering committee at ministry level, to give directions and approve the policy; ii) a core working group, to manage the work of the small groups and draft the policy paper; iii) and a national task force, representing all stakeholders, in charge of contributing to the content of the policy.

3. What does a QI policy look like?

Again, because very few countries have such a policy paper, it is difficult to provide a range of options and examples. However, the following topics should be addressed in the policy paper:

- Values, vision, mission, and philosophy. The health system is like an organization, with its own culture. It is important to make explicit the “ideology” behind the strategic decisions that are made. This usually happens during strategic planning sessions where common values as well as differences are discussed. For example, the Ministry of Health can emphasize the importance of “equitable access to healthcare services regardless of income” as a major value that influences the design of the healthcare system. A specific definition of quality of care can be developed, such as the one adopted by the Kyrgyz decision-makers. If this is the case, then the definition must be concrete and measurable.
- Overall Strategy. The conceptual framework can be the graphic representation of the strategy or the strategy can be expressed through short statements such as: promotion of EBM; institutionalization of quality management at facility level; national improvement projects on major diseases; national quality monitoring system; etc. It gives the directions to follow, which will have to be translated into activities and operational plans.
- Functions and activities. The activities to implement can be organized under the functions described above or just focus on the activities directly contributing to improving quality of care and listed under the execution/implementation function. They should be as detailed as possible so that their implementation is clear to everybody. For example, under the promotion of EBM strategy, specific activities can be mentioned: teaching EBM to undergraduates, developing guidelines and protocols, providing access to modern literature through decentralized CME units, etc.
- Stakeholders. The policy paper must list the stakeholders of the healthcare system and describe their roles and responsibilities in implementing the QI strategy.
- Structure. By structure, we mean the organizational chart of the quality improvement strategy, with all stakeholders who play a role on the QI policy. The relationships between stakeholders must be described explicitly. Often, the issues are not as much in the individual components of

the QI system, but in the relationships (or lack thereof) between these components. By relationship, we mean the areas of collaborations that require exchange of information, joint planning and implementation, supervision and evaluation, reporting, and ensuring the continuity of activities from one stakeholder to the next.

- Resources. The sources of funding must be explicitly described, starting with the Ministry of Health and the Government in charge.
- Regulations. Many types of regulations might be needed to allow the national strategy to be implemented. Part of improvement requires to review and update health regulations.

Improving quality is a long-term objective and the national QI strategy should reflect a sound approach over the next 5 years, which seems like a reasonable time before the next phase is planned.

What Structure is Needed to Implement the QI Policy?

We advocate for a small structure to be in charge of facilitating the implementation of the QI national strategy. We are insisting on a facilitating role rather than an implementing one, because we want to avoid the verticalisation of the QI strategy. This small unit should be attached to a very high level of the Ministry of Health and report to the Minister or the deputy-minister on a regular basis. The roles and responsibilities of such a structure are the following:

1. Communicate regularly with all implementing stakeholders in order to document progress and issues with the implementation of the strategy; For example, the Quality Unit will follow-up on the development of agreed upon guidelines and protocols.
2. Contribute to quality improvement by raising system issues and addressing them when they are specifically under the authority of the central level of the MoH; for example, the Quality Unit will develop a mechanism for the Ministry to fund the development of guidelines through a national EBM Center.
3. Strengthen the links between partners and programs, organizations and projects. This requires exchanging information, attending meetings and contributing to various planning sessions. For example, the Quality unit will make sure that the medical equipment procurement unit of the MoH has developed a list of equipment needed from the guidelines developed.
4. Report on progress in the quality strategy to the Ministry of Health and higher authorities; For example, the head of the Quality unit will debrief the Minister every month.
5. Organize specific events such as an annual conference on quality, during which the stakeholders can follow-up on the implementation of the strategy.
6. Identify opportunities for local staff to develop their skills in quality improvement through international conferences and training events.
7. Advocate for improvement in quality of care through sensitization of staff at all levels of the healthcare system.
8. Identify quality improvement opportunities and priority topics for quality improvement efforts and projects.
9. Review health legislation and regulations in order to update them according to available evidence.

This list of functions is by no means exhaustive and it is possible that, in the long term, once quality activities are integrated in the healthcare system that the Quality Unit is not needed anymore and will be dismantled. In the short-term, is unlikely that any policy will be implemented without some sort of a structure in charge of it at the central level.

In Short on the Institutionalization of QI

The institutionalization of quality improvement requires the integration of specific functions in the day-to-day operations of the health care system. Many stakeholders have to join forces to explicitly define their roles and responsibilities in fulfilling functions as diverse as: leading for quality; facilitating implementation of QI activities; advising on quality; advocating for quality; implementing QI activities; teaching for QI; monitoring and evaluating QI activities; doing research on QI; communicating on QI.

The QI activities themselves are many, including but not limited to: the promotion of evidence-based medical practices; the monitoring of quality of care and health system performance at appropriate levels of the healthcare system; the implementation of specific quality improvement projects and efforts through repeated CQI cycles; the development of charters to guarantee patients' rights; the assessment of new medical technology; the licensing and certification of health professionals; the accreditation of health facilities; patient safety programs; the training of human resources for health in QI techniques, including performance assessment and teamwork.

The institutionalization of QI is a complex task and we recommend the development of a national QI policy as well as the establishment of a small Quality Unit at a very high level of the MOH to facilitate its implementation.

XI. Frequent Issues with Quality Improvement Efforts

There are countless issues on the road to improvement. We selected three that, from our experience, are the most common:

1. **Lack of leadership.** Success in all improvement efforts depends heavily on the existence of a champion, someone who is enthusiast about quality improvement, is genuinely concerned about quality issues, is not afraid of dealing with complexity, enjoys chasing the devil hidden in the details, and can communicate a clear vision of a better system to others. In our experience, these characters are rather the exception than the norm, and are more likely to be found at the peripheral level of the system than at the top. Usually, the staff of a big bureaucracy such as a Ministry of Health is afraid to be punished for being too pro-active on issues that involve some risk-taking. At the facility level, we have met many dedicated staff who are aware of the changes needed and commit their daily energy to serving the patients, but they are usually very discouraged by aspects of a system that they have no control over and do not fully comprehend. Obviously, not everybody is a leader, but leaders are needed at every level of the health system so that they reinforce and support each other towards the achievement of a common objective. It does not mean that we should give up on improvement efforts when leaders are “absent” or leadership is not effective. On the contrary, involving high-level decision-makers in facility-based improvement projects is one way to build (or reveal) their leadership. But the bottom-line is that someone needs to take the initiative to start an improvement effort and in our experience an outsider (external change agent) such as a specific program/partner has an important role to play to facilitate the interaction between bottom-up activities (delivering care) and top-down activities (issuing regulations).
2. **Resistance to change.** It is human nature to be adverse to change, because every change involves risks and uncertainty. Although we believe that everybody wins if quality improves, it is difficult to anticipate the feeling of some that they will be losers if changes occur. We have witnessed the improvement efforts of many teams that focus on measurement and have little success in implementing system changes. In our experience, the main reason is a mix of the following factors: lack of creativity for doing things differently (such as organizing healthcare services); fear of being blamed and punished for implementing a change that proves not to be effective; lack of autonomy to make decisions in a centralized command and control system; disillusion and discouragement with the current system; lack of trust between staff and employer, health workers and managers, and sometimes patients and healthcare providers; lack of motivation (more disincentives than incentives) to do more than just the minimum routine; poor understanding of roles and responsibilities for improving the system.
3. **Wrong focus.** Many efforts do not lead to improvement because they were not properly designed, and/or implemented and/or supported with the right focus. Most common mistakes are: unclear and non measurable improvement objectives; improvement indicators that do not relate to the objectives; wrong identification and interpretation of the root-causes of system performance; interventions and changes that do not address the causes of poor quality; errors in measurement; errors in interpretation of a change in performance; incomplete or flawed implementation of a change. We have encountered many situations where the improvement logic was not followed and the “story” can’t even be written because it did not make any sense. To prevent this situation from happening, technical assistance from an experienced quality improvement expert is needed at all steps of the QI cycle (in the pilot phase of our model).

XII. Conclusion

It is a challenge to write a conclusion for such a document, with the expectation that it will cover all aspects of the quality improvement field through a final and inspiring remark. We decided to share three reflections about our work in Central Asia:

- Although the focus of improvement efforts is on the system, we learned through 10 years of supporting health reform activities in Central Asia that nothing happens if people's issues and concerns are not addressed. People make decisions that are best for themselves and the system they serve, but the most important factor for success is the relationship between partners or stakeholders of the healthcare system. As much as processes and systems need to change, the real changes often come from a shift in mentality, attitude and behavior of people working in that system. While ZdravPlus is not aiming at changing the social culture of the countries in which it works, it is nevertheless influencing the way people think and critically look at what they have been doing and how the bigger healthcare system contributes (or not) to improved health status for the population of Central Asia.
- The dynamic of improvement is very much dependent on the social, political and economic context, which influences what changes are acceptable, feasible and affordable. We have observed that changes are more likely to happen and at a faster pace in decentralized systems where local entrepreneurship is the prevailing culture. It is more difficult to change systems (and therefore to improve performance) in a centralized system with a command-and-control management style that limits the autonomy of peripheral units through regulations. The reform of the health sector needs to contribute to building a more effective but also a simpler system. A sophisticated healthcare system might be advocated by experts who are familiar with the results of complex health system research studies, but it is more difficult for patients and providers to understand the system and to perform appropriately in such an environment.
- The improvement road is a bumpy one, alternating between the excitement of seeing a change producing results and the frustrations of not being able to deal with system issues for which the level of authority is not clear or they are not able (or willing) to address the issues. Sometimes, the only result of an improvement effort is a better understanding of the system and the issues that must be addressed. If this is so, the improvement journey was worth the effort as it is as important to understand why efforts failed as much as it is to understand why they succeeded.

Improvements rarely come by chance and a structured effort is more likely to produce results if it is organized around the principles and methods described in this document. The ZdravPlus project will continue supporting improvement efforts that will help Central Asia countries complete the reform of their health sectors.

XIII. List of Annexes

Annexes Referred to in the Text

Annex 1: Specificities of the Field of Quality Improvement



Annex 2: Job-aid developed by ZdravPlus for the Quality Management Team

Annex 3: Example of an Indicator Form

Annex 4: Systems View of Immunization Services

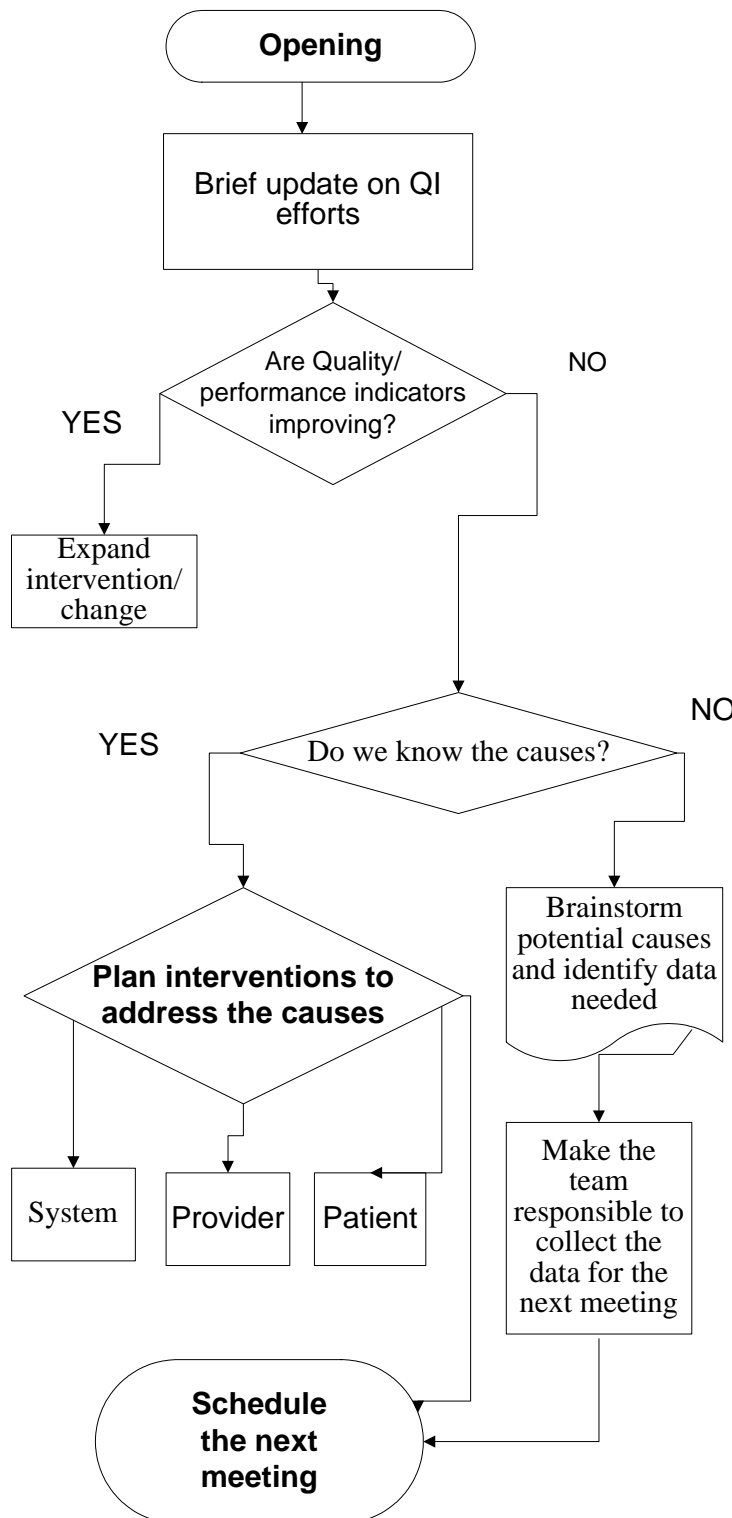
Annex 5: Application of the Quality Management Principles to the Quality Improvement Cycle

ANNEX 1: Specificities of the Field of Quality Improvement

Discipline 	Clinical Care	Public Health	Quality
Criteria 			
Source of knowledge	Medicine Nursing care	Epidemiology, statistics, behavior change models	Management Statistics Qualitative disciplines
Focus/Target	Individual patient	Population	System
Nature of the action	Care/Treatment	Intervention	Change
Nature of the relationship between stakeholders	Interpersonal Communication between provider and patient	Interaction between activities and target groups	Teamwork
Duration of the effects	Depends on the health condition and available solutions	Depends how root-cause of problems are addressed	As long as the change is implemented, the new system will perform at an enhanced level of performance
Expected Impact	Cure Limited disability	Prevention Protection	System's Performance Providers' performance
Main skills	Medicine Scientific knowledge Interpersonal Communication	Planning Management Training Epidemiology Statistics Health information systems	Team facilitation System's Analysis Performance measurement Standards setting Creative thinking

ANNEX 2: Job-Aid for the Quality Management Team

JOB AID FOR QUALITY IMPROVEMENT SESSIONS



Explanatory notes

1. Introduction to the Quality Improvement (QI) session. Review of the previous QI session

2. Rayon Coordinators give an update on QI efforts, including previous interventions/changes, their impact on QI indicators (using data from ACCESS database). This stage requires interpretation of the run charts based on following steps:

- is there a change in quality/performance?
- is the change an improvement or not?
- why did quality/performance improve or not?

3. If the previous intervention lead to improvement, then members should discuss and plan its expansion in the oblast.

4. If quality/performance is not satisfactory, then reasons should be identified through brainstorming. If there is not enough information on the causes of poor performance, then make the team (Rayon Coordinator, Chief Specialists) responsible to collect necessary data by the next meeting

5. If the reason for poor quality/performance is known, then plan intervention/changes to address the causes. This change can target the system and/or the health provider and/or the patient. Assign responsibilities within the team for testing the intervention/change.

This logic can be repeated during the same QI session using the same algorithm to address other QI projects on different topics or other issues on the same topic

6. Schedule the next meeting

ANNEX 3: Indicator Form Developed for the Monitoring of Quality of Care to Patients with Hypertension in Ferghana

Name of Indicator: Hypertension screening rate

Standard			Definition of Indicator: What will it measure?			Composition of the Indicator: How to calculate it?				Steps of the Process and Sources of Data			
A health worker (nurse or physician) checks blood pressure of all patients ³¹ at each contact with SVP and s/he records the results in the patient’s medical record and/or any other existing logbook			Out of all patients that came to the SVP within one month how many had their blood pressure measured as recorded in a medical record			<u>Denominator (D)</u> : Number of all patients who visited the health facility this month				1. Count all patients aged 18 and older registered in the <i>Admission Journal</i> who came this month = <u>D</u> .			
						<u>Numerator (N)</u> : Number of patients who had their blood pressure measured this month as recorded				2. Count all patients aged 18 and older registered in the <i>Tonometry Journal</i> who had their blood pressure checked this month = <u>N</u> .			
Month	Jan	Feb	March	April	May	June	July	Aug	Sept	Oct	Nov	Dec	
N													
D													
N/D x 100													

Unit of the Indicator (number, percent, other): %

Frequency of Data Collection: Monthly collection and calculation

Responsible person(s) for data collection: Head physician

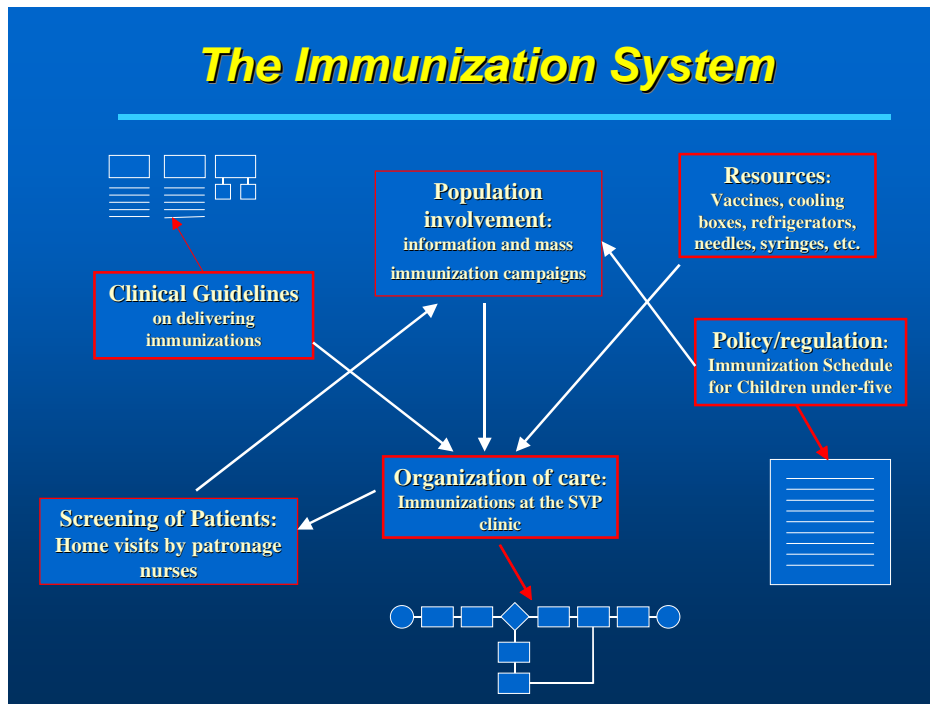
³¹ The word “patient” refers to any customer enrolled to the health facility aged 18 and older
An Introduction to the Field of Quality Improvement

Expected trend of the Indicator: Increase, up to 100%

Potential issues: Errors in calculation; omission in recording all patients in the admission journal.

ANNEX 4: Systems View of Healthcare Services

The Immunization System



Systems' View of the Healthcare System for Prenatal Care

Inputs	Processes	Outcomes
<ul style="list-style-type: none"> •Pregnant women •GPs •Obstetrician •Midwife •Nurse •Medical equipment •Office equipment •Medical record •Drugs •Clinical guidelines •Etc. 	<ul style="list-style-type: none"> •Appointment schedule •History taking •Reporting on records •Physical examination •Lab exams •Clinical assessment •Counseling •Planning and prescribing treatment •Etc. 	<ul style="list-style-type: none"> •Pregnant women receive prenatal care according to standards •High-risk pregnancies are identified •Serious clinical care issues are properly managed •Women end-up having a normal delivery and child is alive and healthy •Etc.



QIP Startup Meeting
Fergana, October 2002



ANNEX 5: Application of the Quality Management Principles at each step of a Quality Improvement Project/Cycle

Stages Principles	Stage 1: Planning	Stage 2: Implementation			Stage 3: Evaluation
		Setup Improvement Objectives	Develop Interventions	Implement Changes	
Patient-focus	Identify issues expressed by patients (complaints) with clinical care Obtain information from patients about their perspectives on the quality of care	Develop objectives that reflect patients' perspectives, expectations and satisfaction	Study the healthcare system from patient's perspective in order to identify targets for interventions Involve patients in root-cause analysis and ideas for interventions/changes	Involve the patients in the implementation of the changes Implement interventions that target also the patients	Involve the patient in the evaluation of the improvement effort
Systems-focus	Identify issues with overall system performance through review of statistics/studies and discussion with providers/managers	Develop improvement objectives that reflect a focus on system performance, and not limited to providers' performance	Perform root-cause analysis with a focus on identifying issues with the system of care, not limited to providers and patients Identify changes to test in processes and systems of care	Implement changes in processes and systems of care using the PDSA tool	Identify system issues that were addressed and the ones that were not
Information-focus	Gather relevant information about issues with quality of care and performance of the healthcare system	Validate the information that led to identifying priority issues and improvement objectives Set up the quality monitoring system	Gather information to confirm the causes of poor quality and performance Generate ideas for changes based on existing evidence or common-sense	Verify that the interventions/changes are implemented as planned	Evaluate how well the quality monitoring system performed and the need for refinement
Team-focus	Establish the teams that are needed (improvement and management)	Get team consensus about the quality objectives to achieve Finalize the composition of permanent teams	Involve all team members in the root-cause analysis Reorganize/create ad-hoc teams as needed	Assign a role to each team member in the implementation	Evaluate the satisfaction and performance of team members
Communication-focus	Communicate to a relevant audience of stakeholders the preparation of a structured QI effort	Communicate expectations on achievements and processes to all members of the team	Communicate the results of root-cause analysis and ideas for changes/interventions to all stakeholders involved and to all targets of changes	Keep team informed of progress in implementation of changes Inform team of impact of changes	Involve everybody in drawing lessons from the project Publish a short report on the improvement effort
Leadership-focus	Identify the leaders who need to approve and take ownership of the project	Get the leaders' approval for the improvement objectives	Get leaders' approval of interventions and changes to be tested	Inform the leadership of progress and issues in implementation of changes	Evaluate how the leadership perceived the project and make recommendations for future work

Reference materials

We are listing here the main sources of information that we used or that we would recommend to those who would like to know more about the field of quality improvement:

On Pilot Quality Improvement Projects and the QI Cycle:

Langley, G., K.Nolan, T.Nolan, C.Norman, and L.Provost. 1996. *The Improvement Guide: a Practical Approach to Enhancing Organizational Performance*. Josey-Bass Publishers.

Massoud, R., K.Askov, J.Reinke, L.M.Franco, T.Bornstein, E.Knebel, and C.MacAulay. 2001. A Modern Paradigm for Improving Healthcare Quality. QA Monograph Series 1(1). Bethesda, MD: Published for the U.S. Agency for International Development (USAID) by the Quality Assurance Project.

Scholtes, P., B.Joiner, and B.Streibel. 2003. *The Team Handbook*. Third Edition. Oriel Incorporated.

On the Replication of Improvements:

Rogers, E. 2003. *Diffusion of Innovation*. Fifth Edition. Free Press.

IHI. 2004. *The Spread Planner*. Institute for Healthcare Improvement, Boston, Massachusetts. 2004.

WHO. 2004. *An Approach to Rapid Scale-Up: Using HIV/AIDS Treatment and Care as an Example*. HIV/AIDS, Tuberculosis and Malaria Evidence and Information for Policy, World Health Organization.

On the Institutionalization of Quality Improvements:

Franco, L.M., D.R.Silimperi, T.Veldhuyzen van Zanten, C.MacAulay, K.Askov, B.Bouchet, and L.Marquez. 2002. *Sustaining Quality of Healthcare: Institutionalization of Quality Assurance*. QA Monograph Series 2(1). Bethesda, MD: Published for the U.S. Agency for International Development (USAID) by the Quality Assurance Project.

Shaw, C. and I.Kalo. 2002. *A Background for National Quality Policies in Health Systems*. WHO Regional Office for Europe.

Bouchet, B. 2003. *Development of the Quality Improvement Concept Paper in Kyrgyzstan*. Trip Report. ZdravPlus Project.

On the Development of Standards and EBM:

Ashton, J. *Taxonomy of Health System Standards*. Bethesda, MD: Published for the U.S. Agency for International Development (USAID) by the Quality Assurance Project.

SIGN. 2004. *SIGN 50: A Guideline Developers' Handbook*. SIGN website.

On the Measurement of Quality:

Donabedian, A. 2003. *An Introduction to Quality Assurance in Health Care*. Oxford University Press.

Marshall, M., R. Brook & al. 2003. *Measuring General Practice: A Demonstration Project to Develop and Test a Set of Primary Care Clinical Quality Indicators*. The University of Manchester and the RAND Corporation. Published by the Nuffield Trust.

Useful websites:

www.ihl.org: the website of the Institute for Healthcare Improvement. Boston, Massachusetts, USA.

www.qaproject.org: the website of the Quality Assurance Project. Bethesda, Maryland, USA.

www.ahrq.org: the website of the Agency for Healthcare Research and Quality. Rockville, Maryland, USA.

www.isqua.org.au: the website of the International Society for Quality in Health Care. Melbourne, Australia.

www.jcaho.org: the website of the Joint Commission for Accreditation of Healthcare Organizations. Chicago, USA.

www.modern.nhs.uk: the website of the NHS Modernization Agency. London, Great Britain.

www.nice.org.uk: the website of The National Institute for Clinical Excellence. Great Britain.

www.sign.ac.uk: the website of the Scottish Intercollegiate Guidelines Network. Great Britain.